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(54) **APPARATUS AND METHODS FOR REMOVING LYMPH NODES OR ANCHORING INTO TISSUE DURING A TRANSLUMENAL PROCEDURE**

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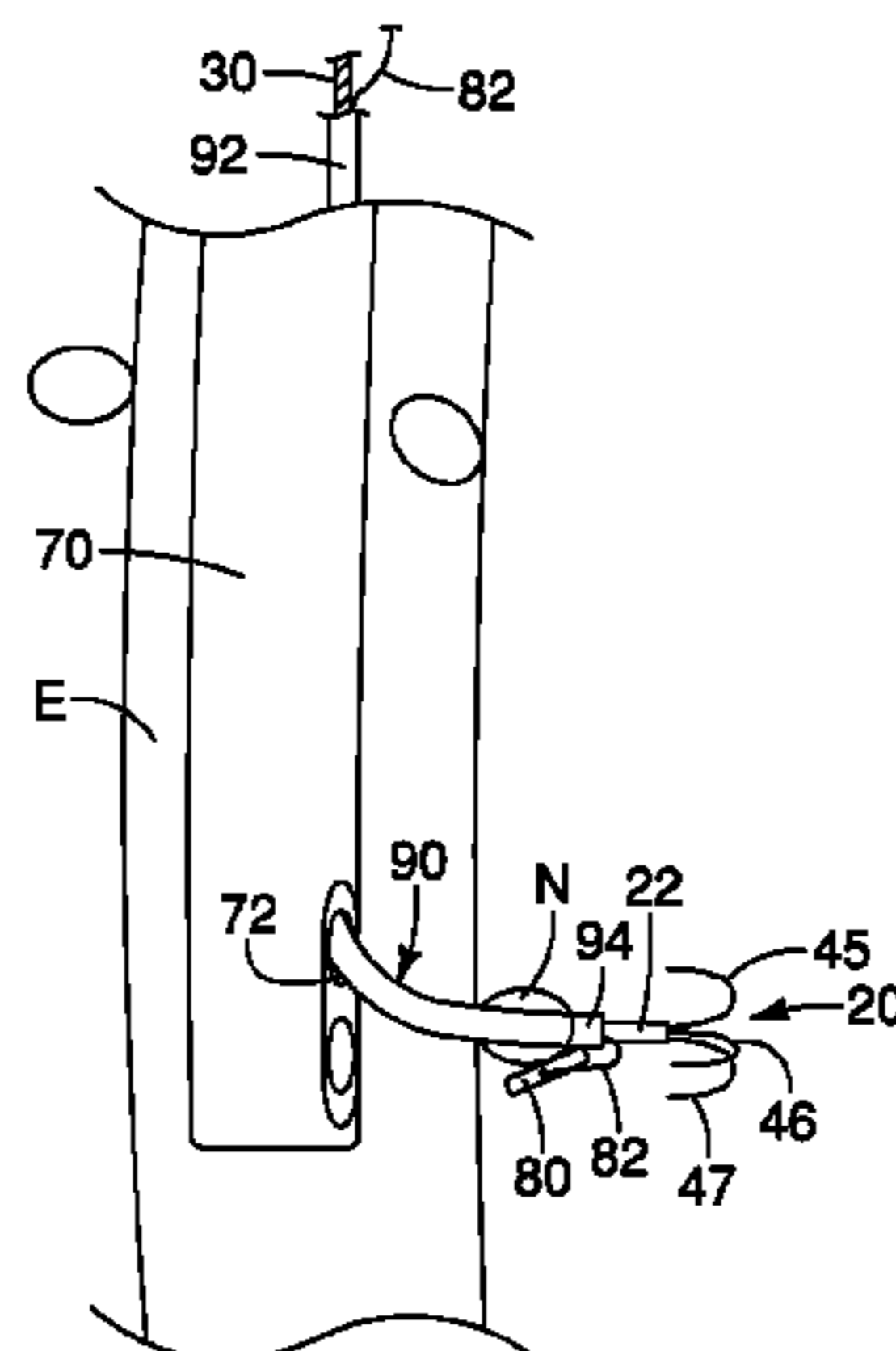
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(57) **ABSTRACT**

The present embodiments provide apparatus and methods suitable for removing lymph nodes or providing a tissue anchor during a transluminal procedure. In one embodiment, an apparatus suitable for facilitating removal of a lymph node comprises an expandable device including at least one deployable member having contracted and expanded states. The deployable member may be delivered in the contacted state to a location distal to the lymph node using an insertion tool adapted to be disposed beyond the lymph node. In the expanded state, the deployable member comprises a configuration sized to at least partially circumferentially surround and engage the lymph node. In an alternative embodiment, the deployable member may anchor into an outer portion of a visceral wall to promote stabilization of a system during a medical procedure.

6 Claims, 10 Drawing Sheets



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* cited by examiner

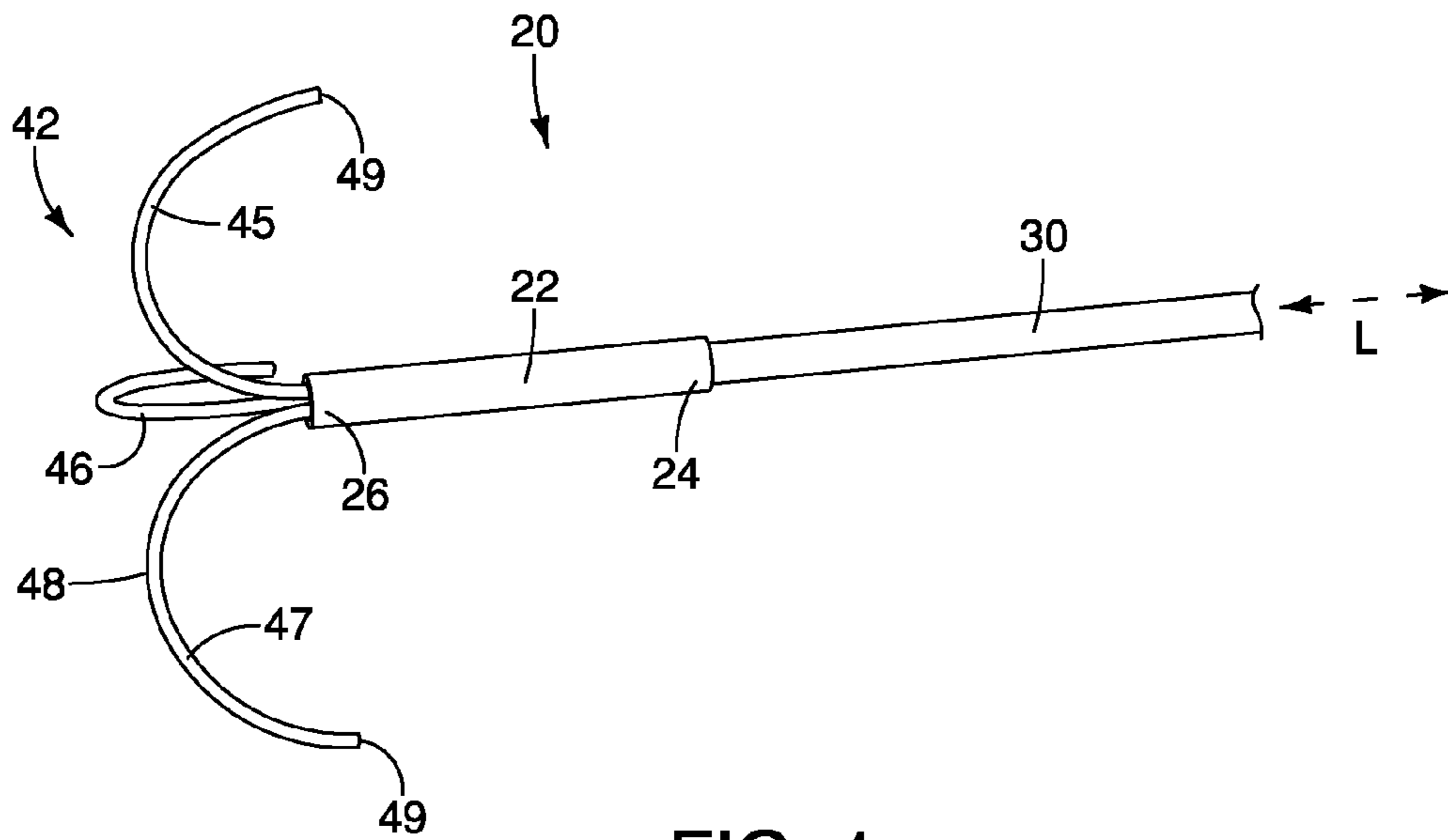


FIG. 1

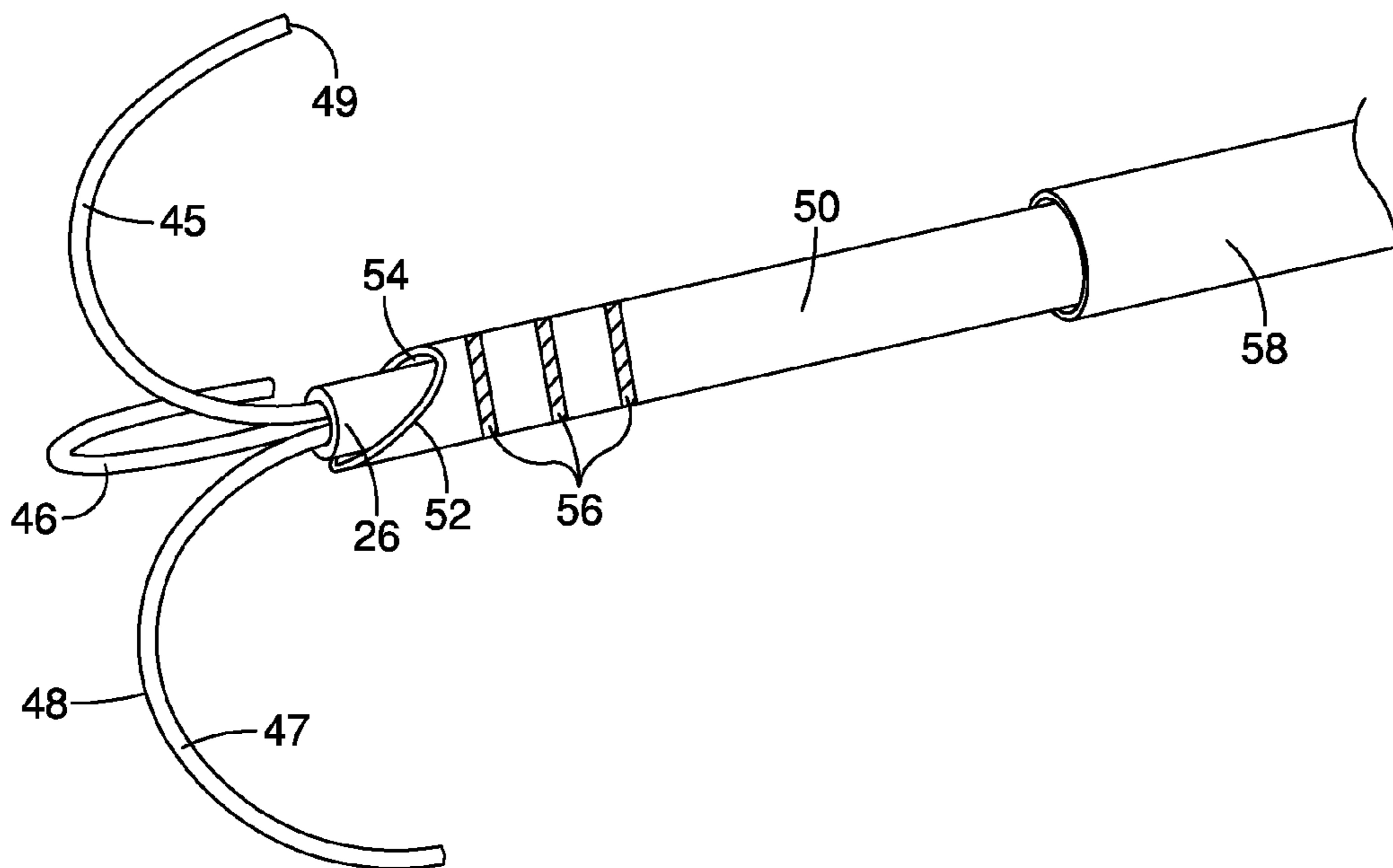


FIG. 2A

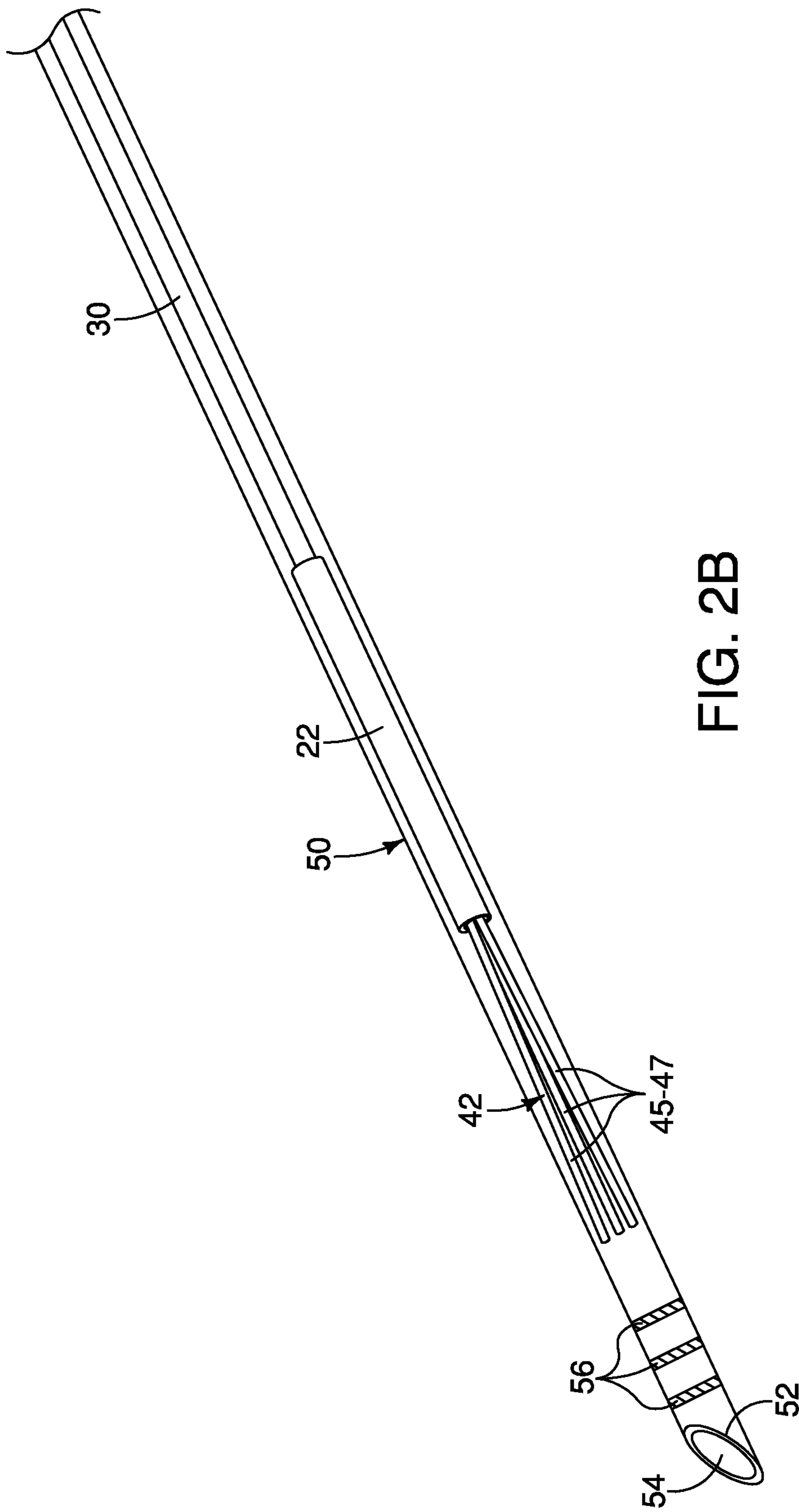


FIG. 2B

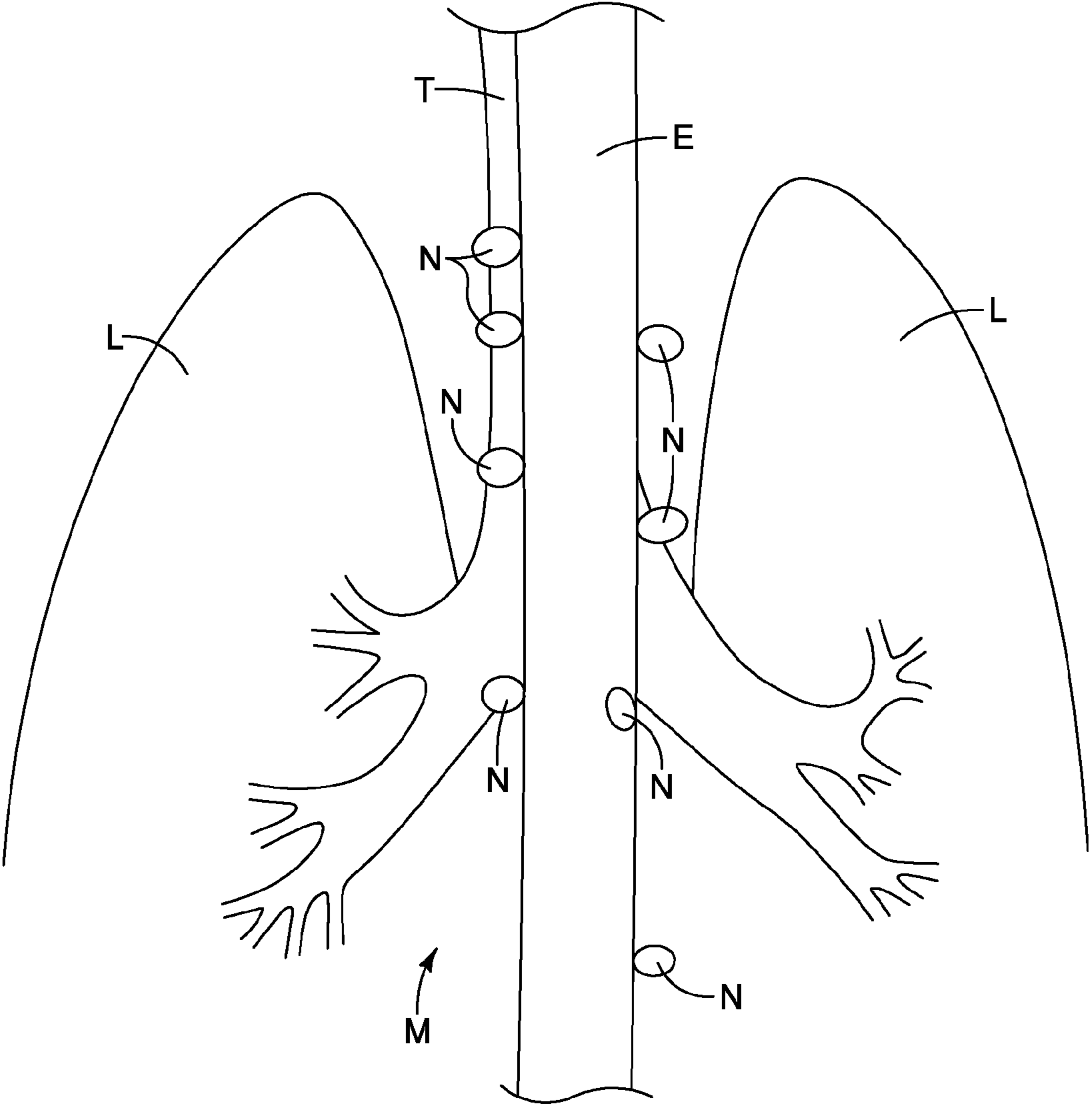


FIG. 3

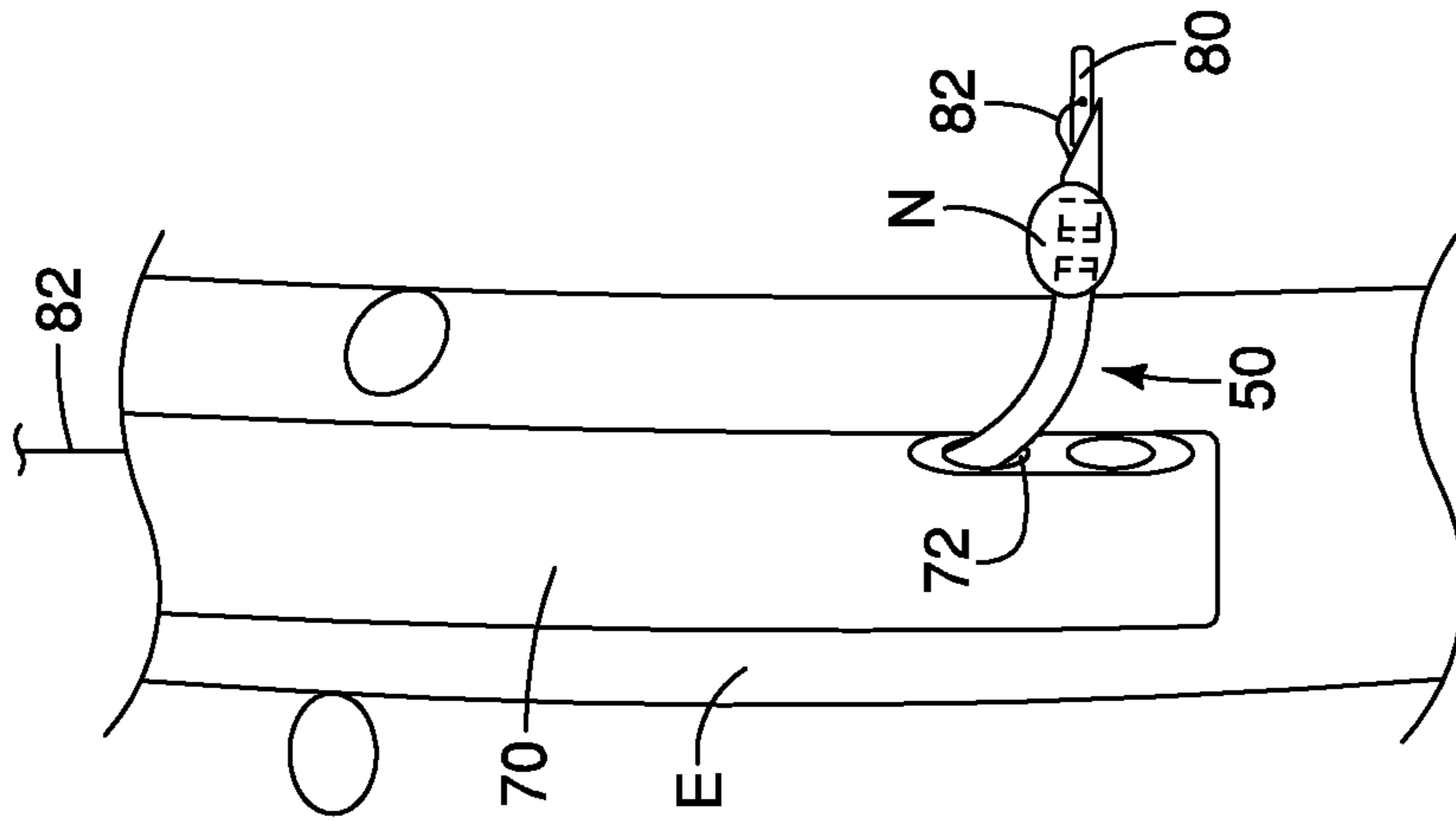


FIG. 4

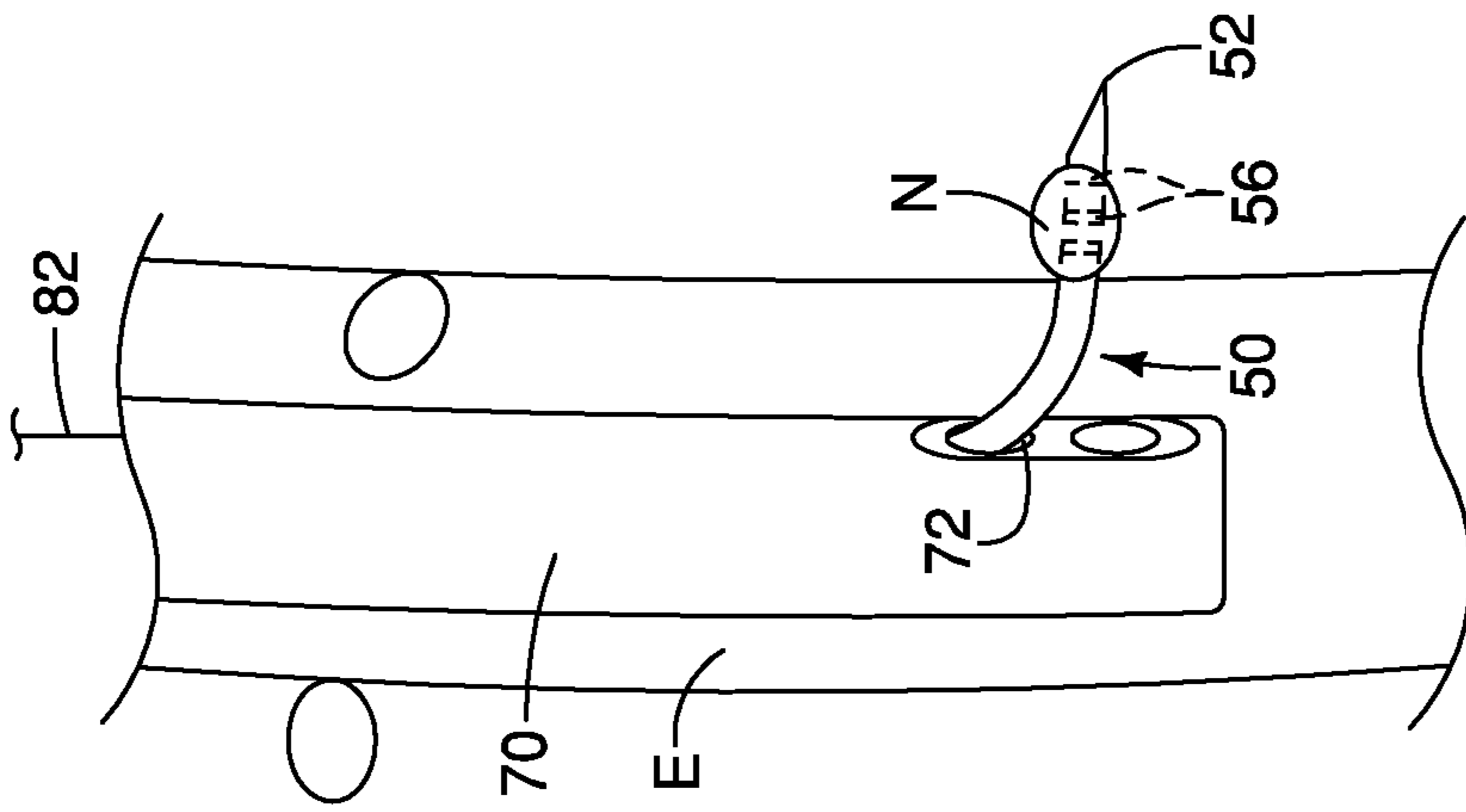


FIG. 5

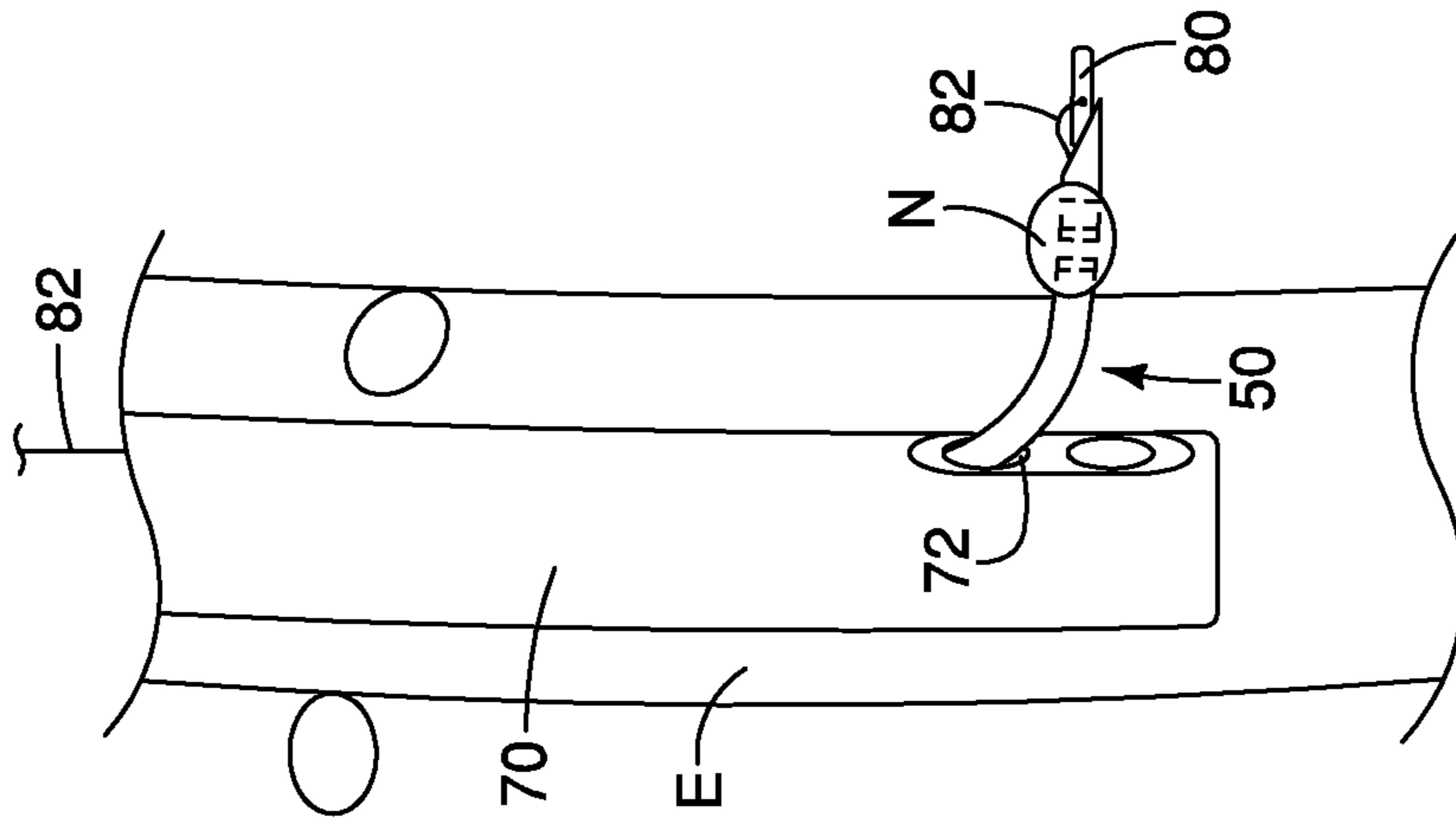


FIG. 6

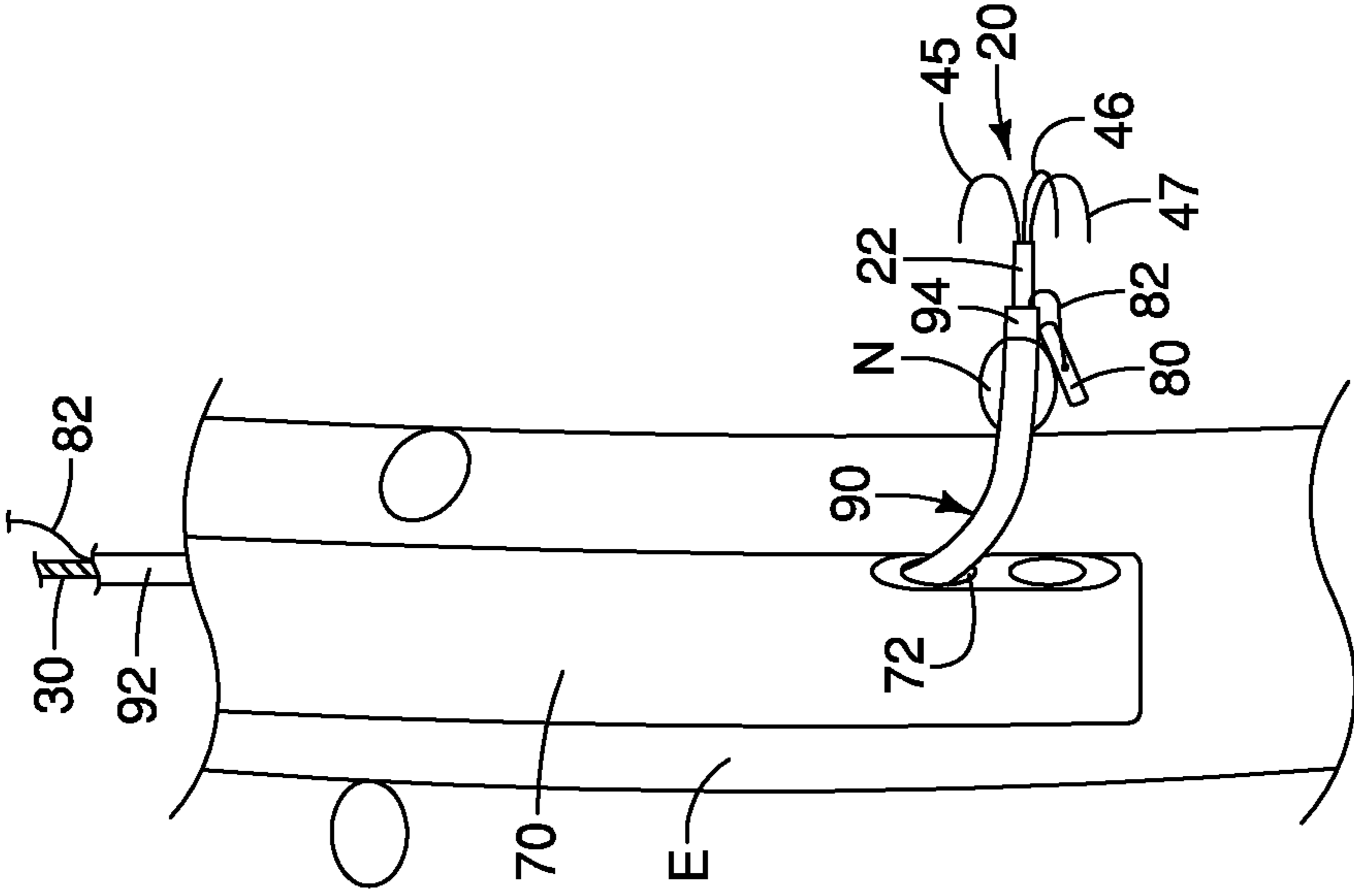


FIG. 9

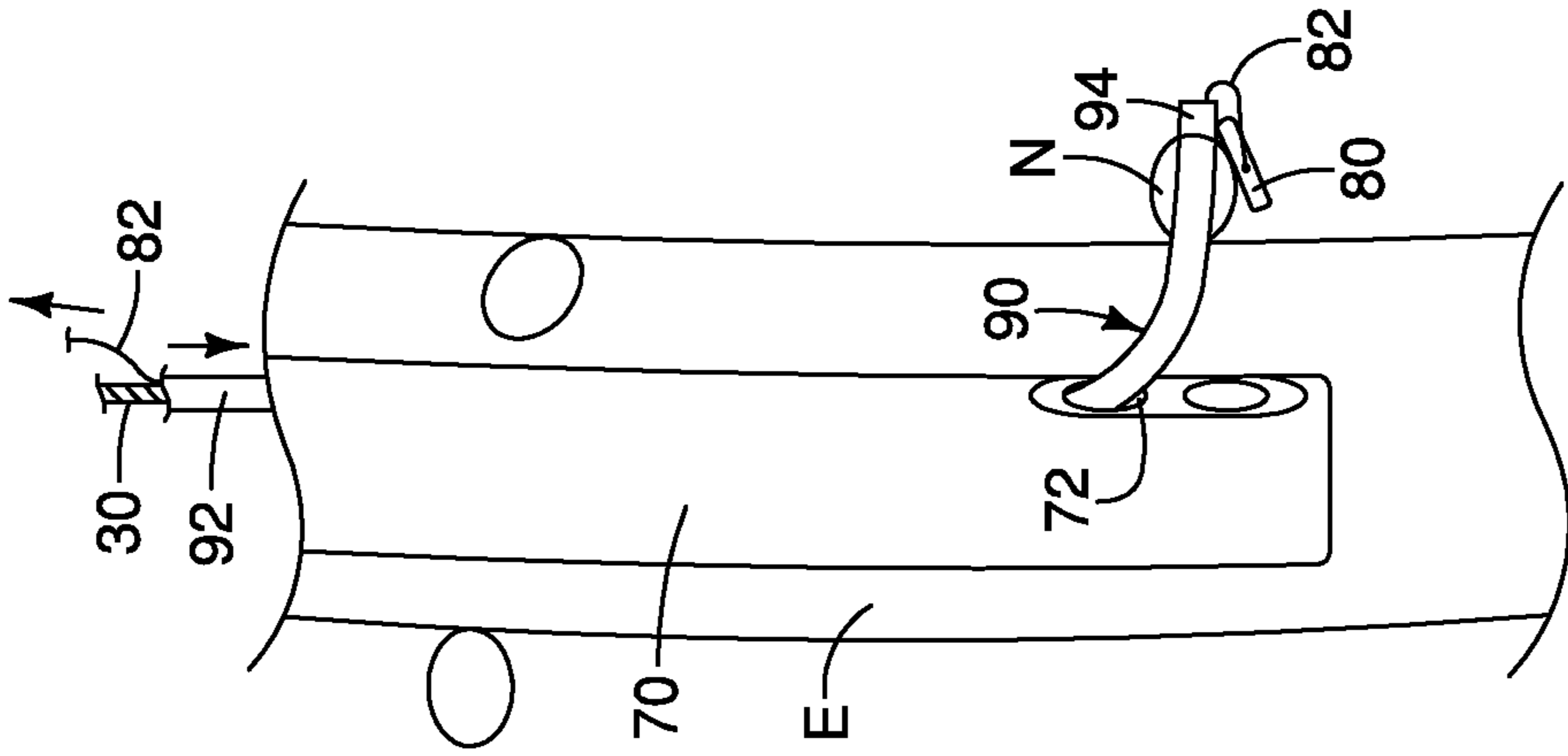


FIG. 8

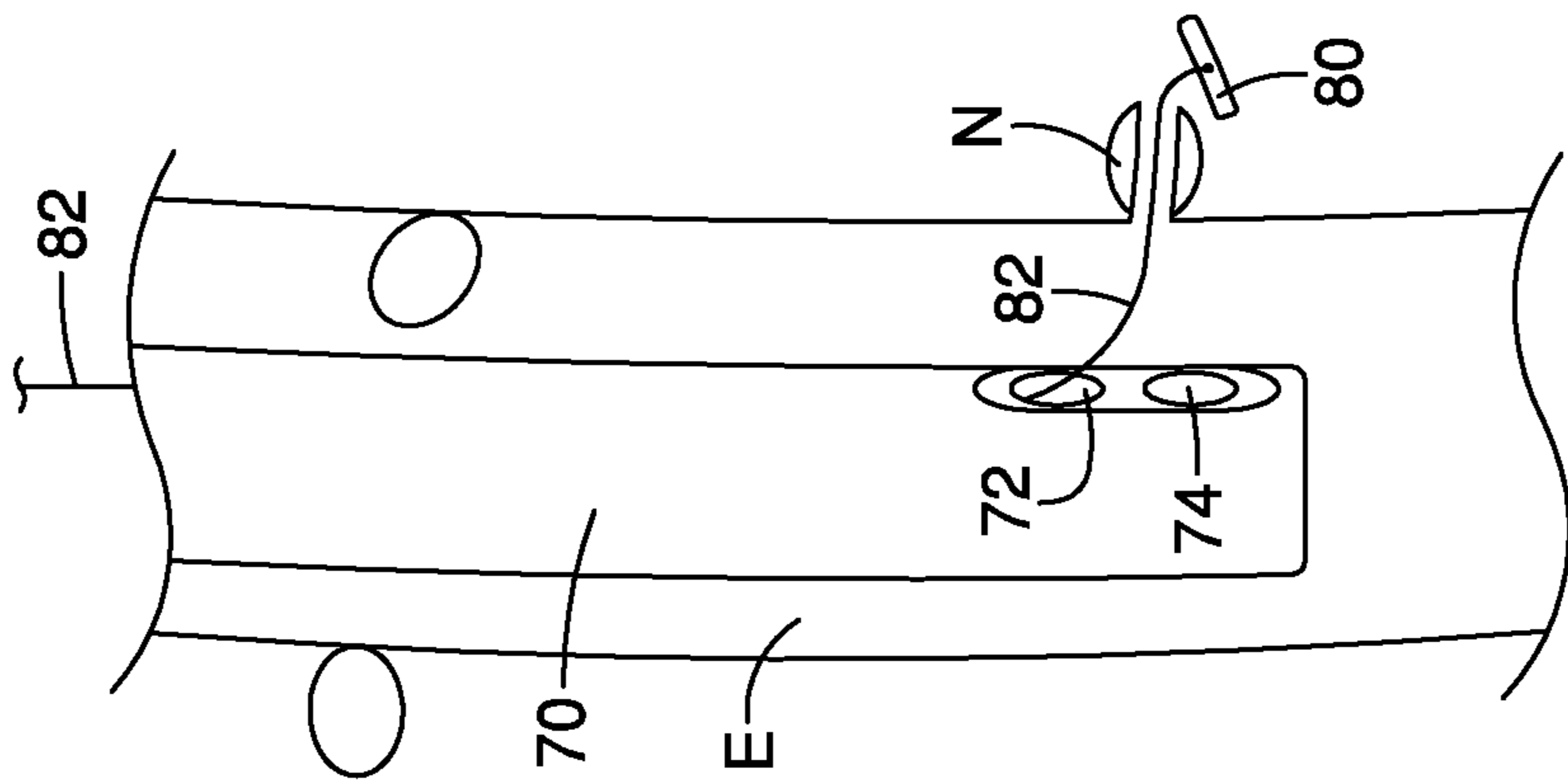


FIG. 7

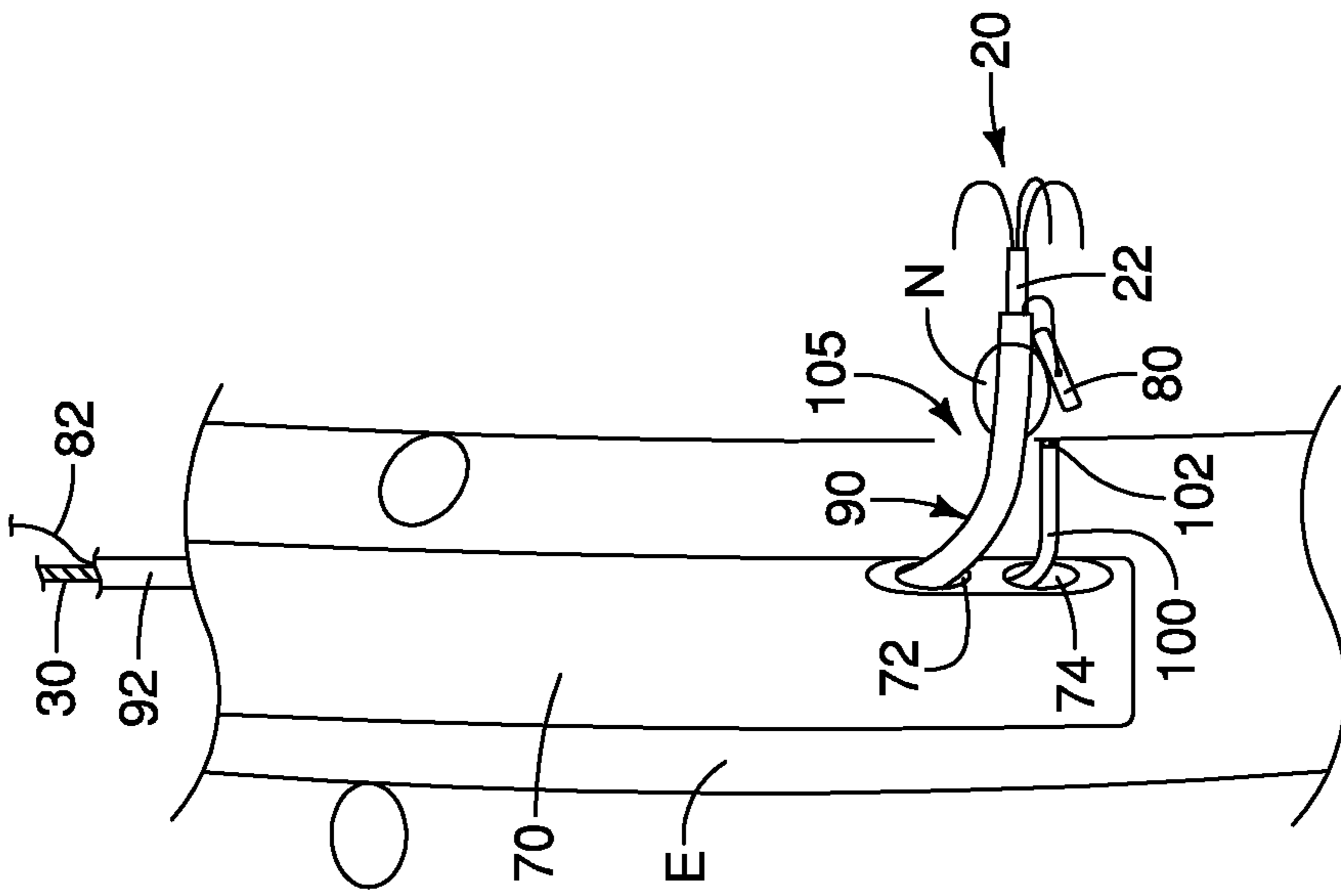


FIG. 10

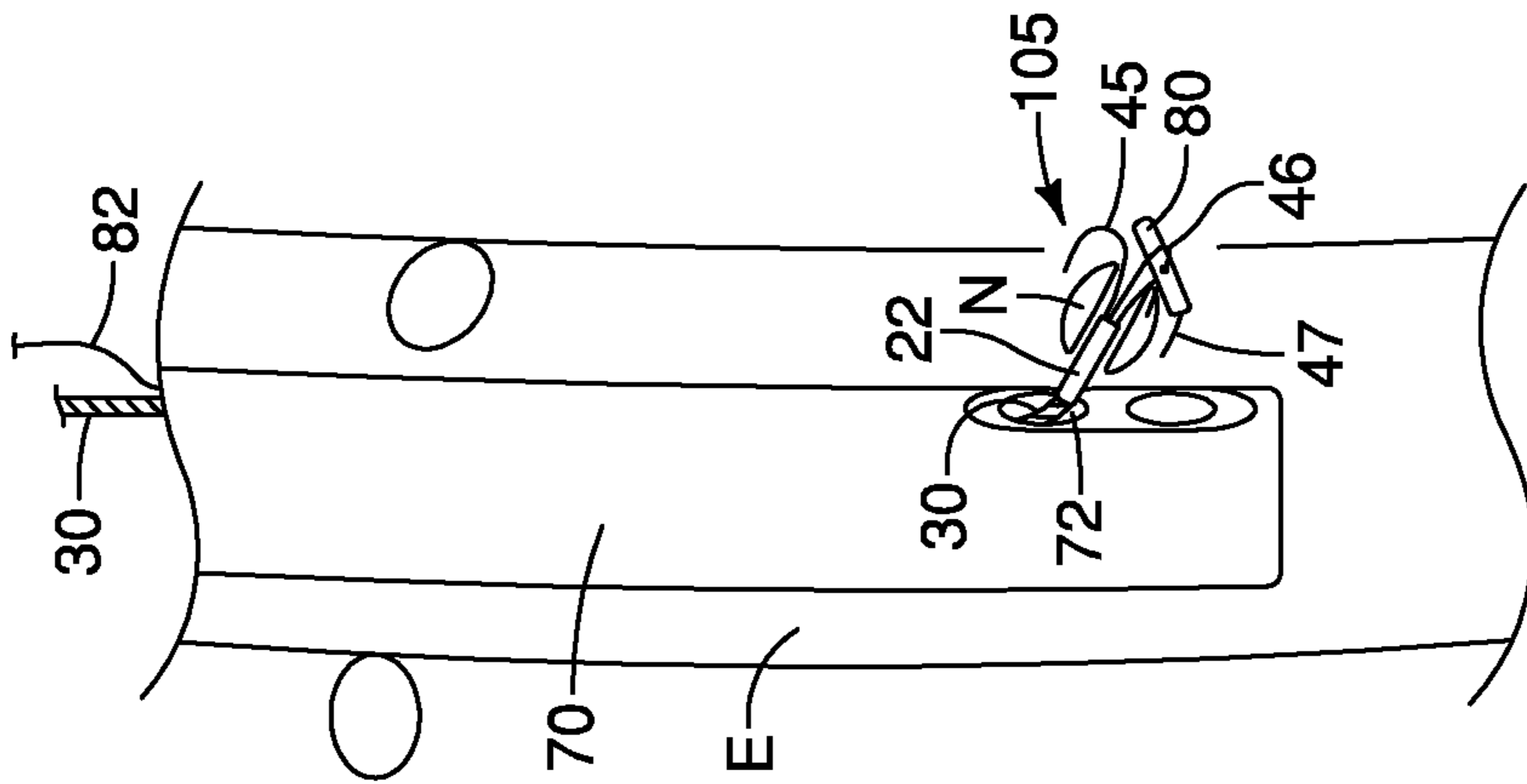


FIG. 11

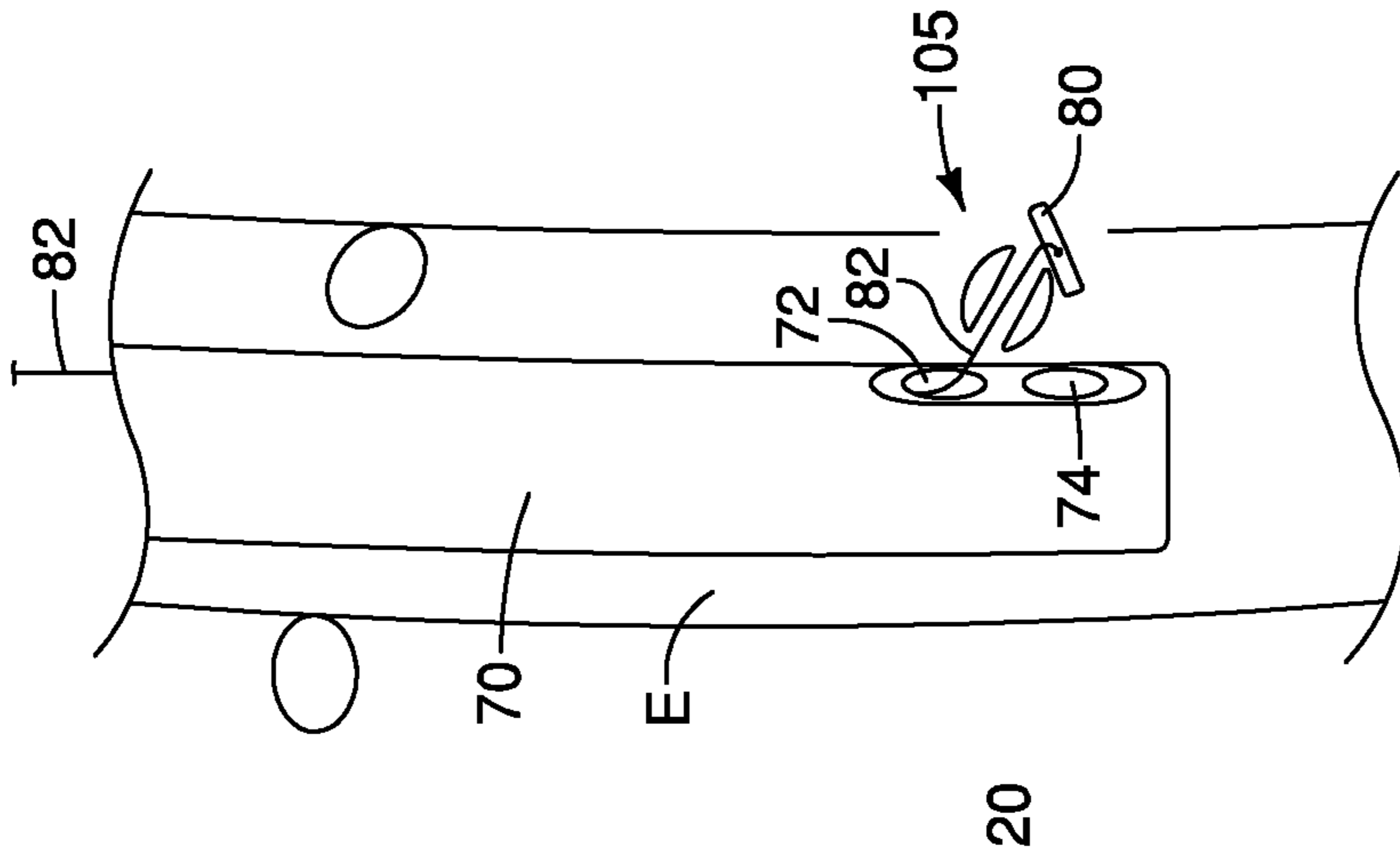


FIG. 12

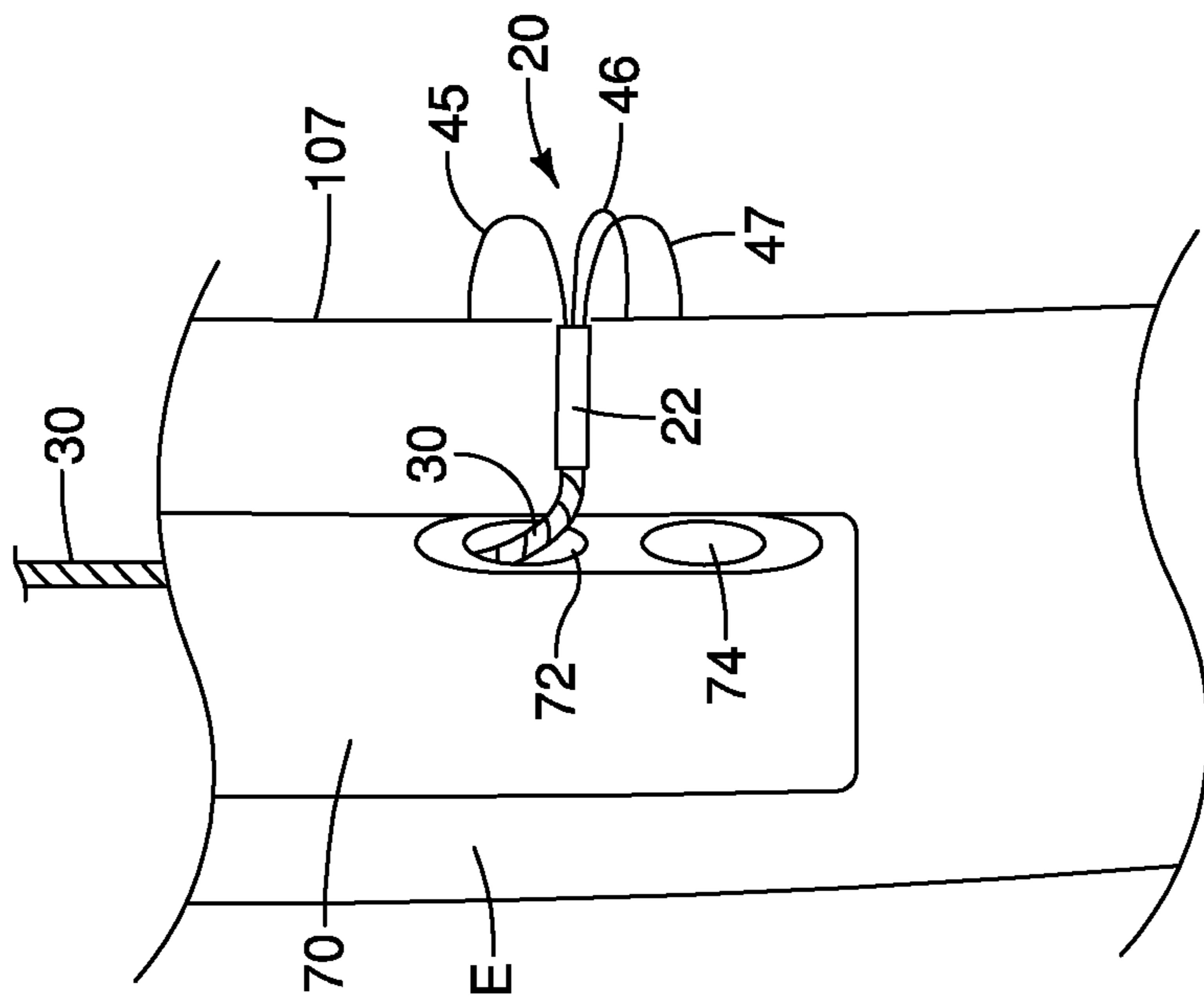


FIG. 14

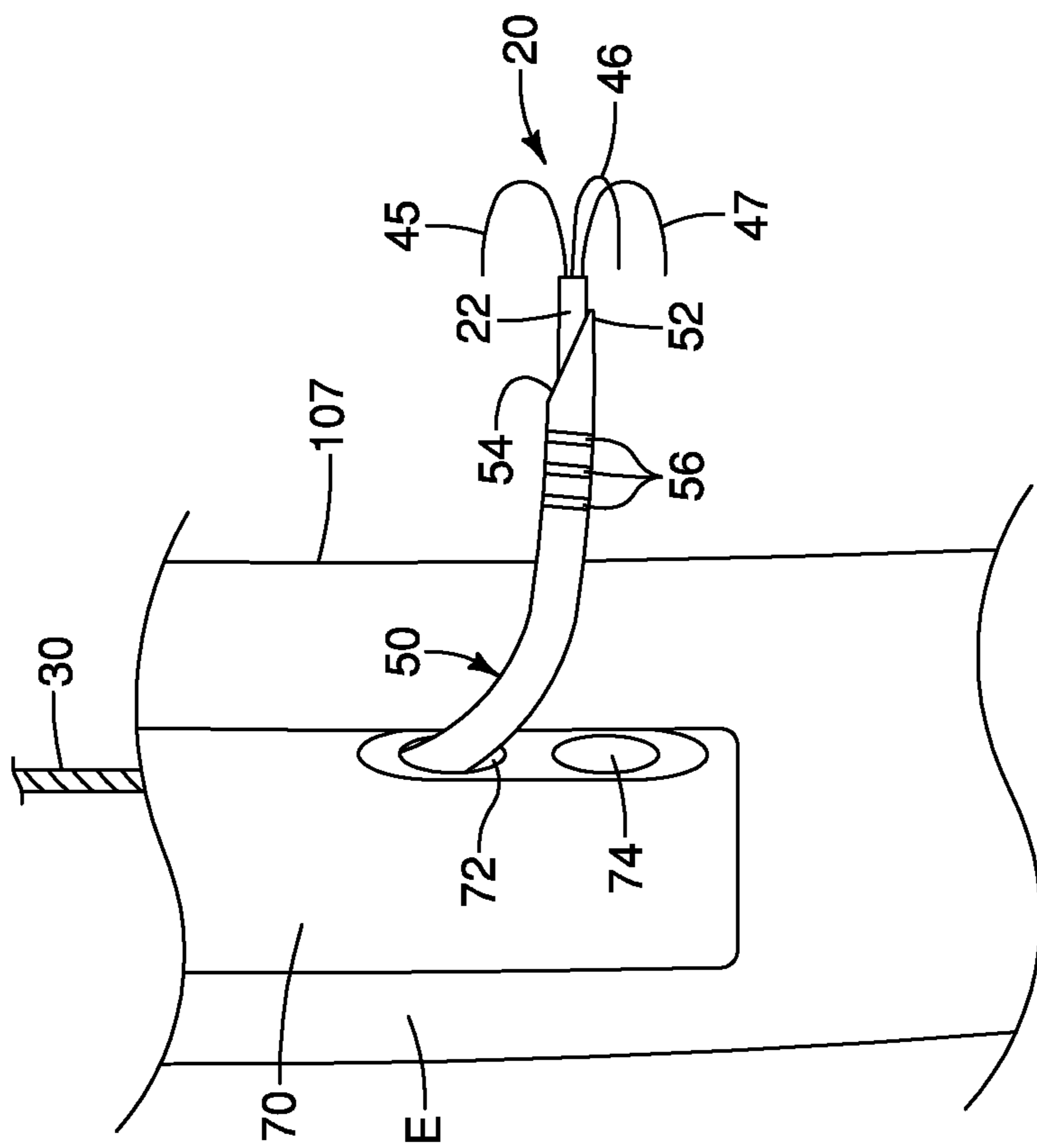


FIG. 13

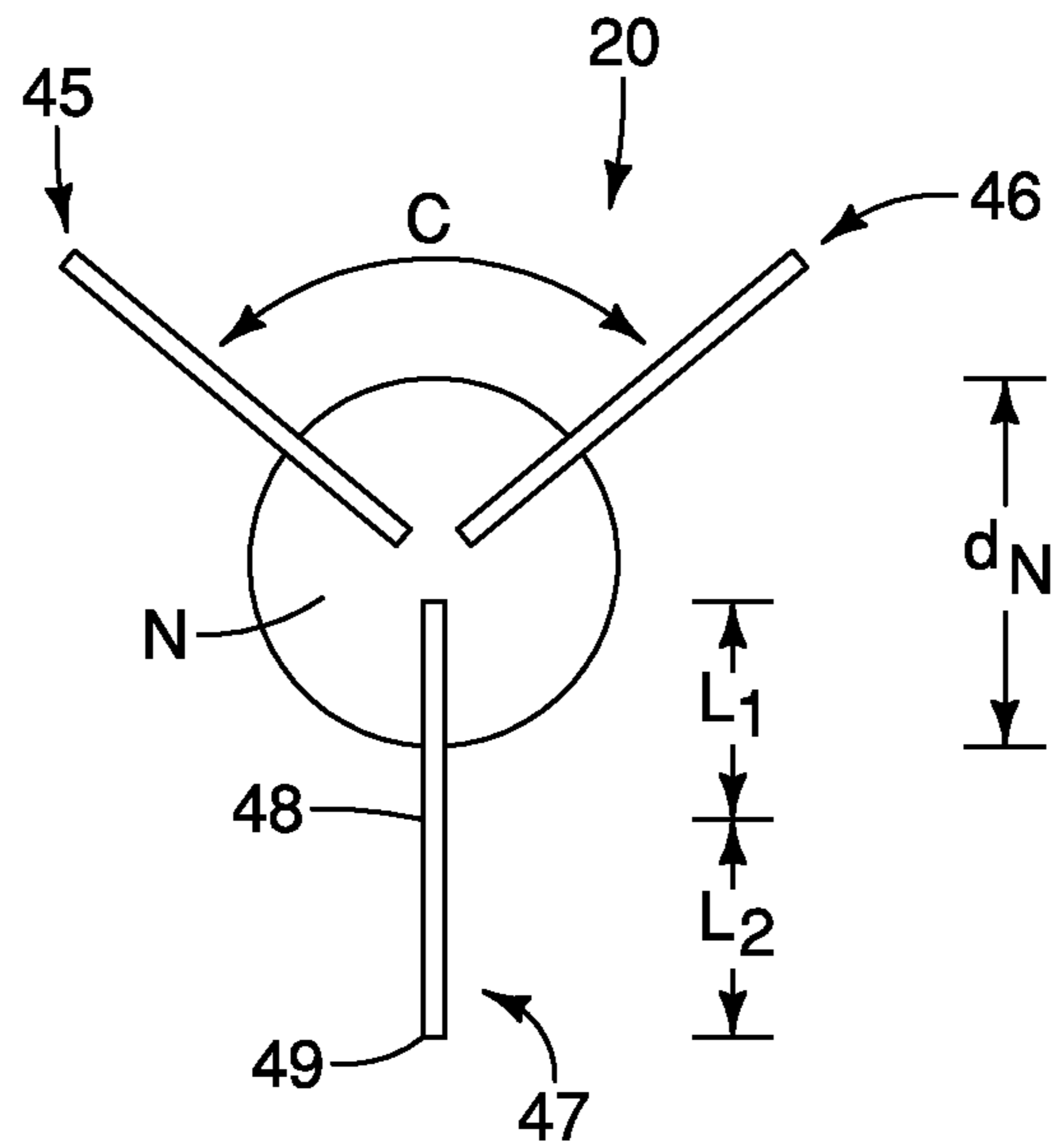


FIG. 15

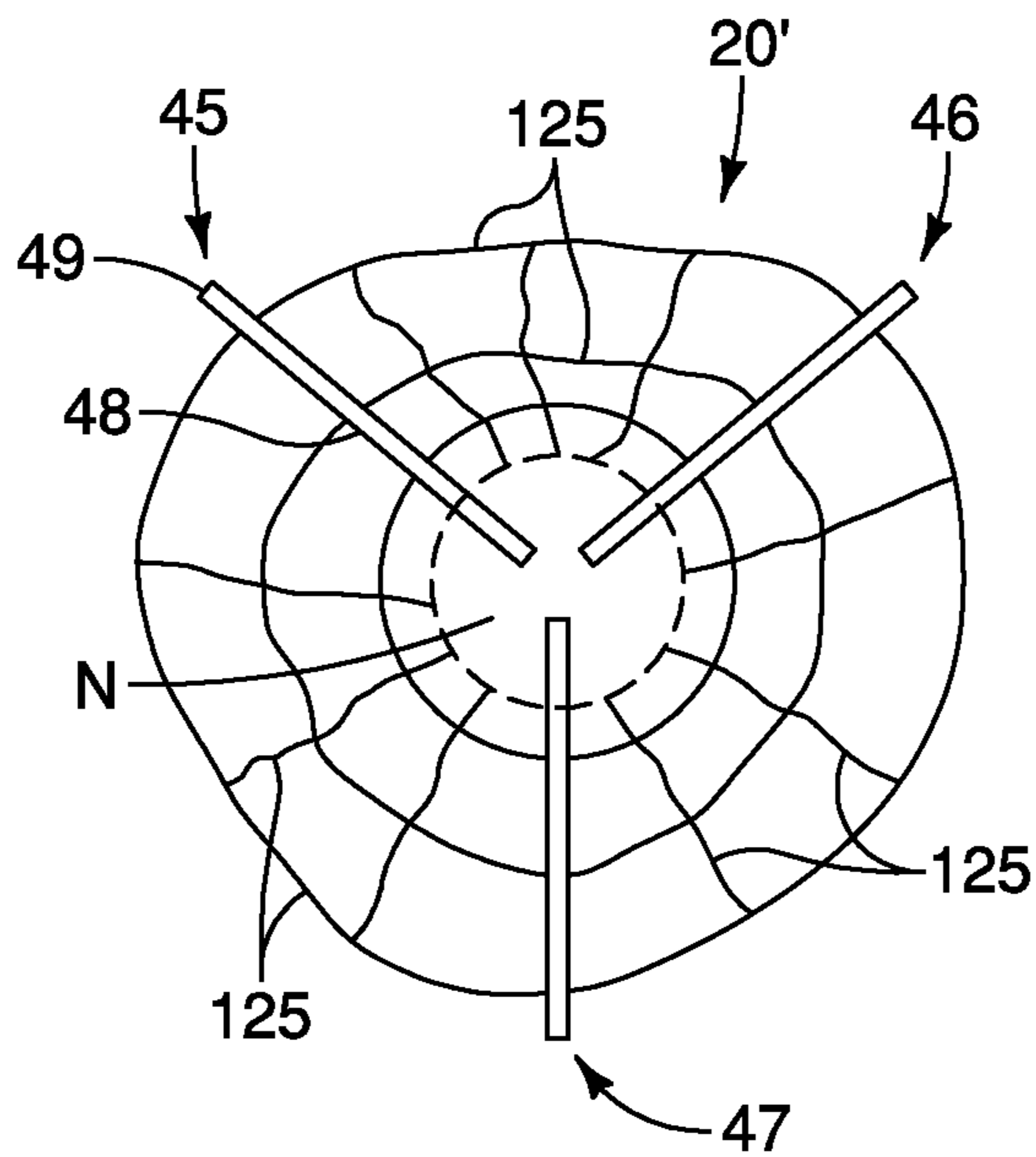


FIG. 16

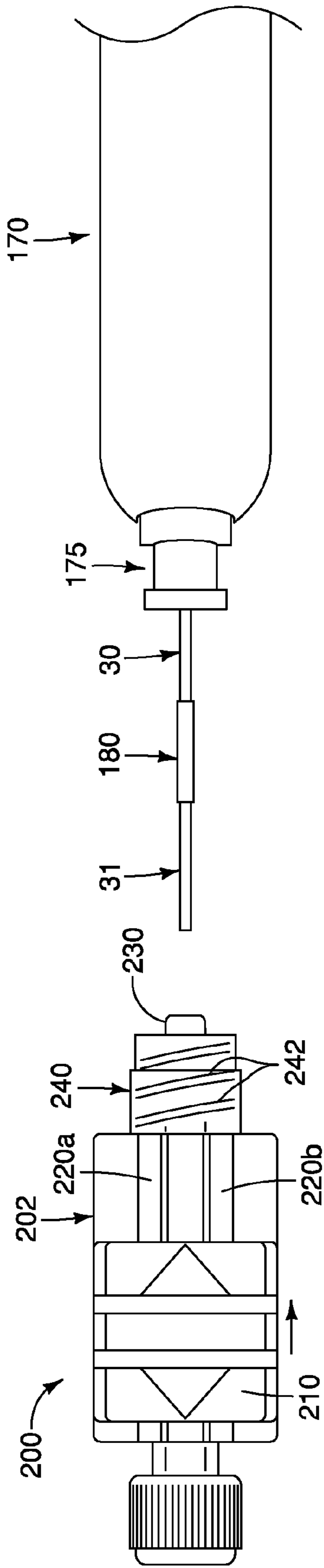


FIG. 17A

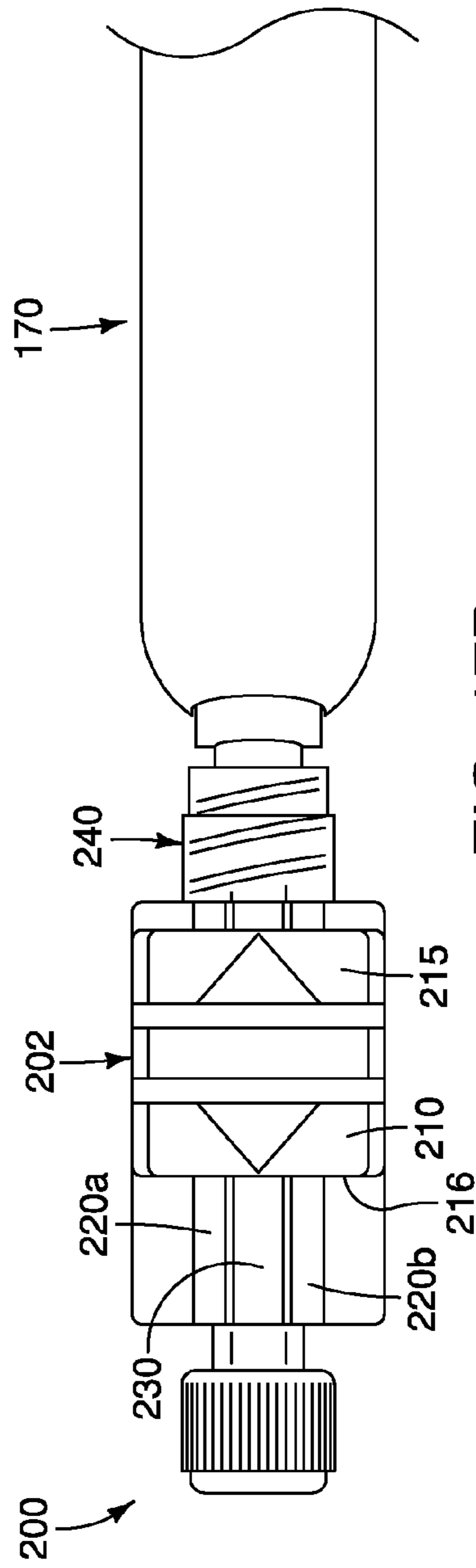


FIG. 17B

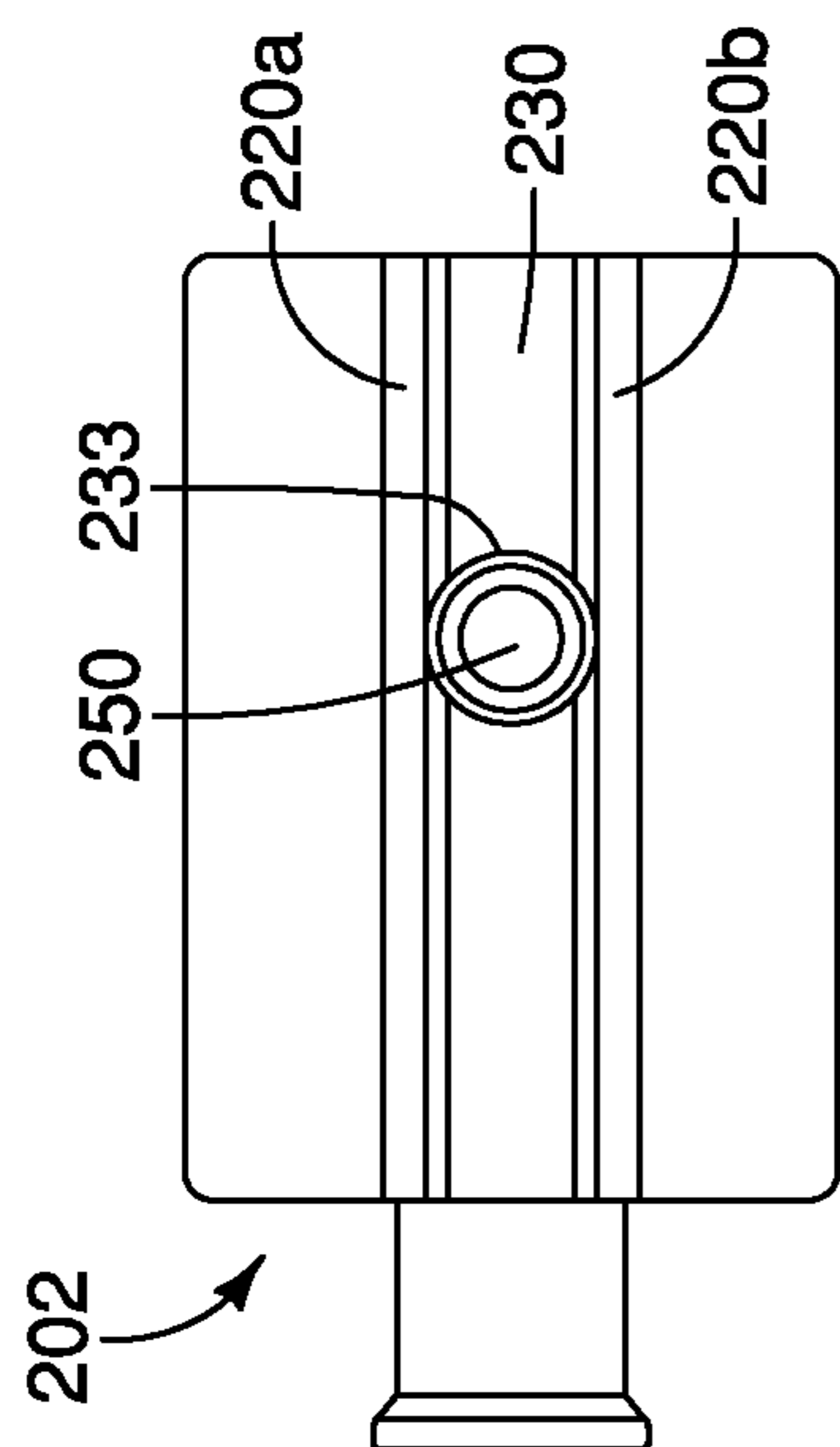


FIG. 18A

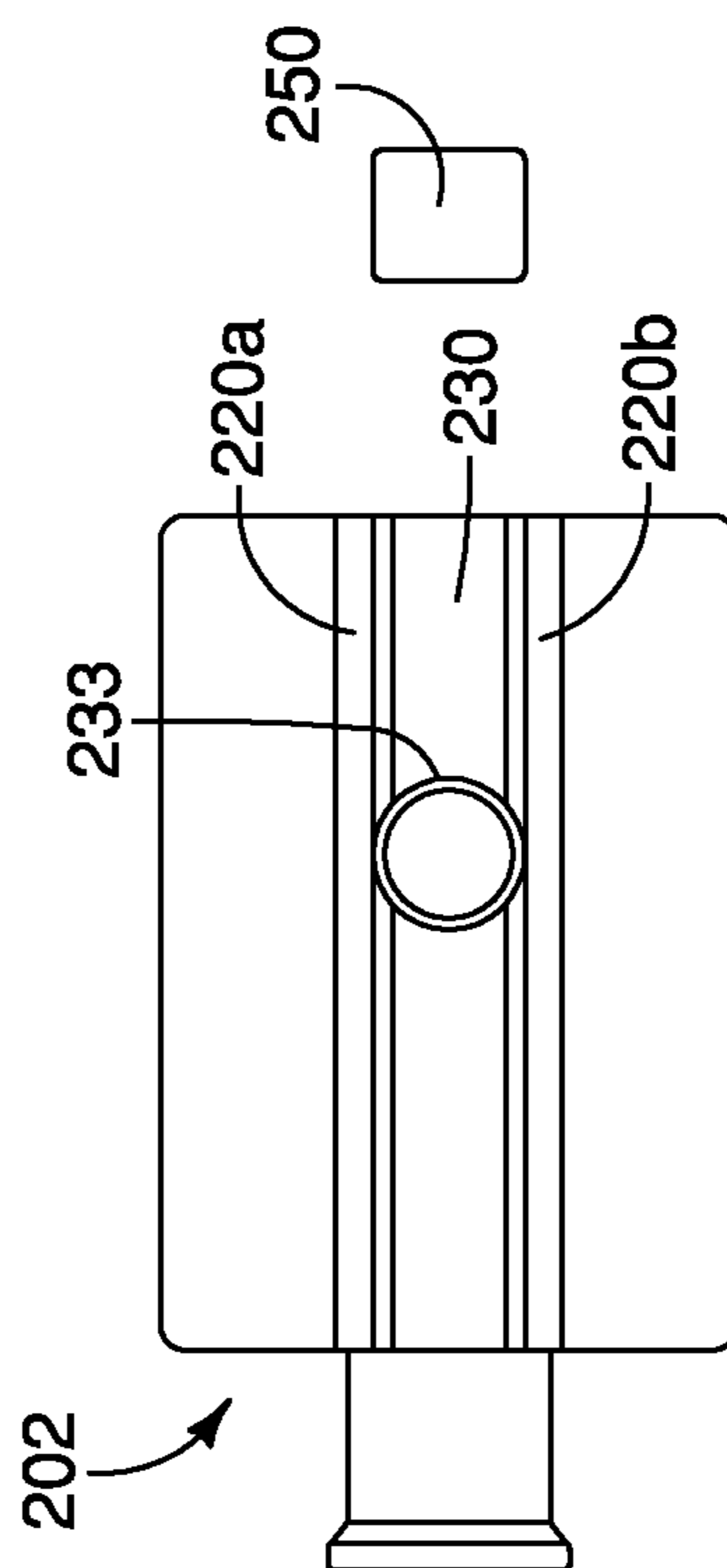


FIG. 18B

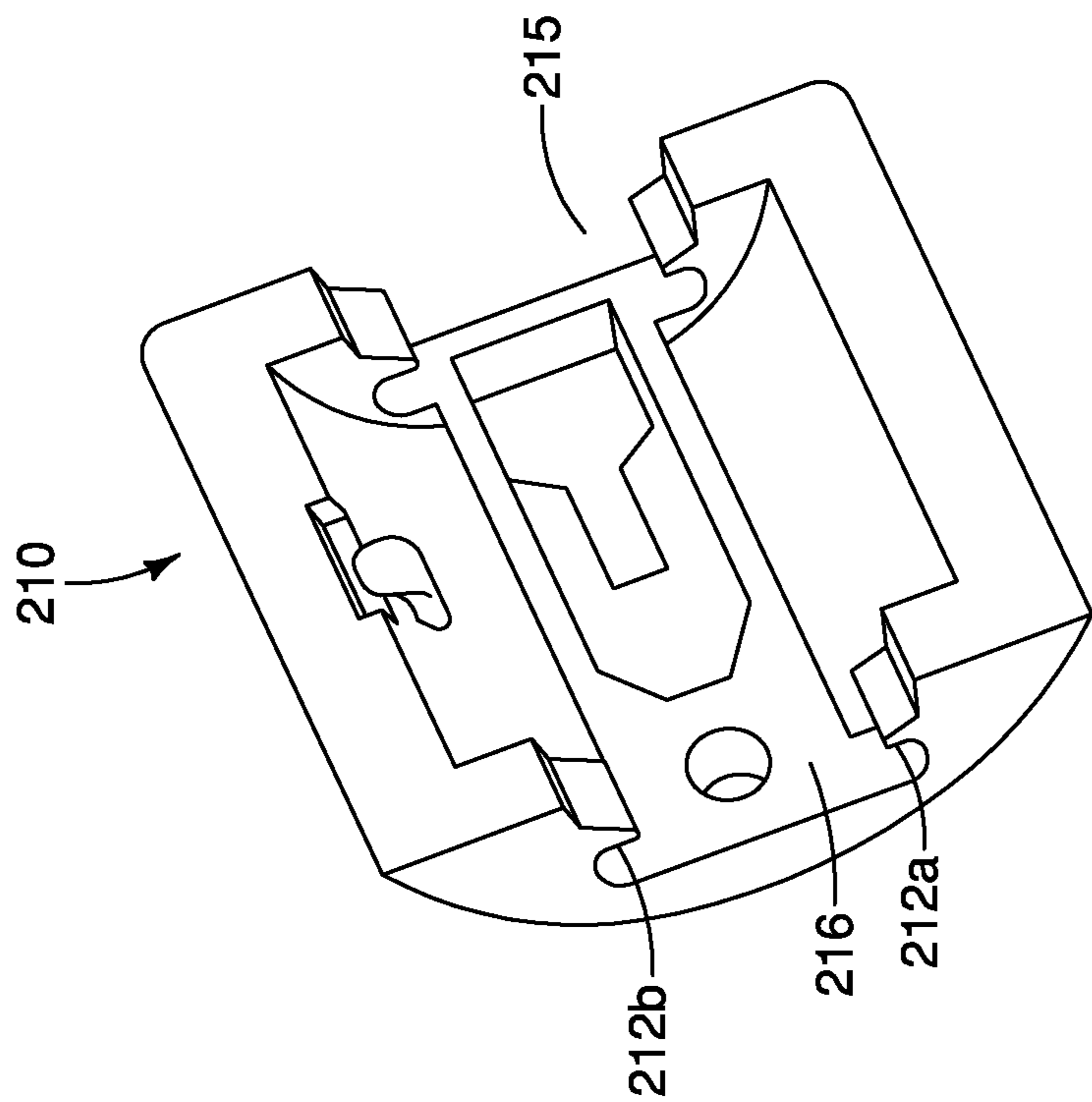


FIG. 19

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**APPARATUS AND METHODS FOR
REMOVING LYMPH NODES OR
ANCHORING INTO TISSUE DURING A
TRANSLUMENAL PROCEDURE**

PRIORITY CLAIM

This invention claims the benefit of priority of U.S. Provisional Application Ser. No. 61/090,115, entitled "Apparatus and Methods for Removing Lymph Nodes or Anchoring into Tissue During a Transluminal Procedure," filed Aug. 19, 2008, the disclosure of which is hereby incorporated by reference in its entirety.

BACKGROUND

The present embodiments relate generally to medical devices, and more particularly, apparatus and methods suitable for removing lymph nodes or providing a tissue anchor during a transluminal medical procedure.

Transluminal procedures generally encompass the formation of perforations in visceral walls to gain access to adjacent structures of the body. For example, culdoscopy was developed over 70 years ago, and involves transvaginally accessing the peritoneal cavity by forming a perforation in the cul de sac. This access to the peritoneal cavity allows medical professionals to visually inspect numerous anatomical structures, as well as perform various procedures such as biopsies or other operations. Many transluminal procedures for gaining access to different body cavities using other bodily lumens have also been developed. Generally, each of the transluminal procedures require the use of several different medical instruments, such as a cutting instrument to form the perforation, an endoscope or other visualizing device to inspect the area or otherwise perform some procedure, and then a closure instrument to close the perforation.

Relatively recent attempts have focused on the transluminal removal of lymph nodes. See Fritscher-Ravens, et al., "Endoscopic Transgastric Lymphadenectomy Using Endoscopic Ultrasound For Selection and Guidance," *Gastrointestinal Endoscopy*, Vol. 63, Issue 2, pp. 302-306 (2006). In this article, selected lymph nodes were punctured with a 19-gauge Endoscopic Ultrasound (EUS) needle. A metal anchor with thread, loaded onto the needle, was placed across the lymph node to pull the node toward the stomach. After gastric-wall dissection with a needle knife at the point of emergence of the thread, the nodes were removed by pulling on the thread and the anchor. The gastric incision then was closed with an endoscopic suturing system.

While the above-referenced article provides a foundation for transluminal removal of lymph nodes, it is an emerging approach and merits the development of new and improved techniques.

SUMMARY

In a first embodiment according to the teachings of the present invention, apparatus and methods are provided for facilitating removal of one or more lymph nodes. The apparatus preferably comprises an expandable device including at least one deployable member having contracted and expanded states. In the expanded state, the deployable member may comprise a parachute-shaped configuration, umbrella-shaped configuration, or other configuration sized to at least partially circumferentially surround the lymph node. The deployable member may be delivered to a location

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distal to the lymph node using an insertion tool adapted to be disposed beyond the lymph node.

In one exemplary method of use, the insertion tool may be advanced beyond the lymph node, and a T-anchor coupled to a suture may be advanced through the insertion tool and ejected at a location distal to the lymph node. Retraction of the suture causes the T-anchor to engage the lymph node and promotes stabilization of the lymph node. Subsequently, the deployable member is advanced distal to the lymph node in the contracted state, using the same insertion device or another insertion device, and assumes the expanded state when advanced distal to the insertion tool and the lymph node.

The lymph node may be removed translumenally through a visceral wall, such as the stomach or esophagus. In one method step, an opening may be created in the visceral wall to facilitate removal of the lymph node. The deployable member may be proximally retracted to engage and retract the lymph node in a proximal direction through the opening in the visceral wall to facilitate removal of the lymph node. A removal device, such as a snare, may then be used to disengage the lymph node from surrounding tissue.

The deployable member may comprise a nickel-titanium alloy that is configured to self-expand to the parachute-shaped configuration or another suitable configuration. The parachute-shaped configuration may be suitable for at least partially circumferentially surrounding the lymph node, and may comprise a strength sufficient to engage and retract the lymph node. In one embodiment, three parachute-shaped deployable members are provided, although greater or fewer deployable members may be used.

In an alternative embodiment, the expandable device may be anchored into tissue to promote stability of a system during a medical procedure. In this method, an insertion tool may be advanced through a first channel of an endoscope, and may pierce through an outer portion of the visceral wall. The expandable device is advanced through the insertion tool and the deployable member is deployed distal to the insertion tool. Upon proximal retraction, the deployable member anchors into the outer portion of the visceral wall. Such anchoring promotes stabilization of the system when additional components are advanced, or procedures performed, through the first channel or a second channel of the endoscope.

Other systems, methods, features and advantages of the invention will be, or will become, apparent to one with skill in the art upon examination of the following figures and detailed description. It is intended that all such additional systems, methods, features and advantages be within the scope of the invention, and be encompassed by the following claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention can be better understood with reference to the following drawings and description. The components in the figures are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention. Moreover, in the figures, like referenced numerals designate corresponding parts throughout the different views.

FIG. 1 is a perspective view of a distal end of an expandable device.

FIG. 2A is a perspective view of a distal region of an insertion tool and the expandable device of FIG. 1.

FIG. 2B is a perspective, cut-away view illustrating the expandable device of FIG. 1 in a delivery configuration.

FIG. 3 is a schematic view illustrating a mediastinal cavity including lymph nodes.

FIGS. 4-12 are exemplary method steps that may be used to remove a lymph node using the expandable device of FIGS. 1-2B.

FIGS. 13-14 are exemplary method steps illustrating use of the expandable device of FIGS. 1-2B as a visceral wall anchor.

FIG. 15 is an end view of a lymph node and the expandable device of FIGS. 1-2B in a deployed state.

FIG. 16 is an end view of a lymph node and an alternative expandable device in a deployed state.

FIGS. 17A-17B are side schematic views of a control assembly that may be removably coupled to a handle, as shown in uncoupled and coupled states, respectively.

FIGS. 18A-18B are side schematic views of the control assembly of FIGS. 17A-17B with a slidable actuator removed for illustrative purposes.

FIG. 19 is a rear perspective view of a slidable actuator of the control assembly of FIGS. 17A-17B.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the present application, the term “proximal” refers to a direction that is generally towards a physician during a medical procedure, while the term “distal” refers to a direction that is generally towards a target site within a patient’s anatomy during a medical procedure.

Referring now to FIG. 1, a first embodiment of an expandable device 20 is shown. In this embodiment, the expandable device 20 comprises at least one tube member 22 having a proximal end 24 and a distal end 26. The expandable device 20 further comprises a distal deployment mechanism 42. In the embodiment of FIG. 1, the distal deployment mechanism 42 comprises three deployable members 45-47. The deployable members 45-47 extend distally from the distal end 26 of the tube member 22, as shown in FIG. 1. Further, a control member 30 may extend proximally from the proximal end 24 of the tube member 22.

The deployable members 45-47 each may be affixed relative to the tube member 22. In one embodiment, each of the deployable members 45-47 may be separate and discrete elements. Accordingly, three separate deployable members may be provided. Specifically, the three deployable members 45-47 may be coupled to the distal end 26 of the tube member 22 using an adhesive, frictional fit, mechanical device or other suitable mechanism.

While three deployable members 45-47 are depicted, it will be apparent that greater or fewer deployable members may be employed. Moreover, the deployable members 45-47 may comprise any shape suitable for engaging, penetrating and/or abutting tissue, or for engaging and capturing a lymph node, for purposes explained further below, and need not necessarily assume the expanded shape depicted in FIGS. 1-2A.

The tube member 22 may comprise any suitable shape and material. Solely by way of example, the tube member 22 may comprise stainless steel or a biocompatible plastic. The tube member 22 may be cylindrically-shaped, as depicted in FIG. 1, which may facilitate insertion through a lumen of an insertion tool 50.

Alternatively, the tube member 22 may be omitted entirely in the case where proximal regions of the deployable members 45-47 are collected together, and preferably affixed together, for example, using a solder or weld. In the latter example, the deployable members 45-47 may be affixed together and soldered or welded directly to a distal portion of the control member 30, or the deployable members 45-47 may be integrally formed as a distal extension of the control

member 30. Further, a plurality of wire members may be braided or twisted together along a main portion of their length, but comprise distal regions configured to deploy to the parachute or umbrella-shaped configurations shown herein, or another configuration suitable for engaging the lymph node

The deployable members 45-47 each comprise a contracted delivery configuration, as shown in FIG. 2B, and further comprise an expanded deployed configuration, as shown in FIGS. 1-2A. In one embodiment, each of the deployable members 45-47 may comprise a parachute or umbrella-shaped configuration in the expanded state, or another configuration suitable for engaging the lymph node, such as a bent or L-shaped configuration.

For example, in the parachute or umbrella-shaped configurations shown, the deployable members 45-47 may comprise a curvature of about 90 to about 360 degrees in the expanded state, and more preferably about 180 degrees, as shown in FIGS. 1-2A. Where the deployable members 45-47 “retroflex” and comprises a curvature of about 180 degrees, an apex 48 is formed and the end regions 49 of the deployable members are oriented substantially parallel to the tube member 22. Moreover, the end regions 49 may be radially spaced apart from one another in the expanded state, as best seen in FIG. 1 and FIG. 15 below. In this configuration, the end regions 49 may be well-suited for engaging and capturing lymph nodes, or engaging, grasping and/or abutting tissue, as explained further below.

The dimensions of the expandable device 20 may be tailored based on a particular surgical procedure, a particular patient’s anatomy and/or other factors. However, for illustrative purposes, in a lymph node removal procedure, a diameter d_N of an exemplary lymph node N may range from about 5 to about 15 mm, as depicted in FIG. 15. In this example, the longitudinal length of the tube member 22 may range from about 2 mm to about 10 mm, the straightened (delivery or non-curved) length of the deployable members 45-47 may range from about 10 mm to about 50 mm, the outer diameter of the tube member 22 may range from about 0.3 mm to about 1.5 mm, and the outer diameter of the deployable members 45-47 may range from about 0.1 mm to about 0.5 mm.

Further, as shown in FIG. 15 below, a longitudinal length L_1 between a longitudinal axis L (see FIG. 1) and the apex 48 may be about 3.2 to 16.0 mm, while a longitudinal length L_2 between the longitudinal axis L and the distal tip 49 may be about 6.4 to 32.0 mm. Such dimensions are provided for reference purposes only and are not intended to be limiting. Therefore, if the diameter d_N of an exemplary lymph node N ranges from about 5 to about 15 mm, the expandable device 20 will be configured to substantially or entirely surround, engage, and facilitate removal of the lymph node N, as depicted in FIG. 15 below.

Referring still to FIG. 15, the three deployable members 45-47 may be spaced apart a circumferential distance C, which may be about 120 degrees. As will be apparent, the deployable members 45-47 may be spaced closer together or further apart to facilitate engagement and capture of a lymph node. If additional deployable members are provided, then the circumferential distance C between deployable members may decrease accordingly.

The deployable members 45-47 may comprise a shape-memory material, such as a nickel-titanium alloy (nitinol). If a shape-memory material such as nitinol is employed, the deployable members 45-47 may be manufactured such that they can assume the preconfigured expanded state shown in FIGS. 1-2A upon application of a certain cold or hot medium. More specifically, a shape-memory material may undergo a

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substantially reversible phase transformation that allows it to “remember” and return to a previous shape or configuration. For example, in the case of nitinol, a transformation between an austenitic phase and a martensitic phase may occur by cooling and/or heating (shape memory effect) or by isothermally applying and/or removing stress (superelastic effect). Austenite is characteristically the stronger phase and martensite is the more easily deformable phase.

In an example of the shape-memory effect, a nickel-titanium alloy having an initial configuration in the austenitic phase may be cooled below a transformation temperature (M_f) to the martensitic phase and then deformed to a second configuration. Upon heating to another transformation temperature (A_f), the material may spontaneously return to its initial, predetermined configuration, as shown in FIG. 1. Generally, the memory effect is one-way, which means that the spontaneous change from one configuration to another occurs only upon heating. However, it is possible to obtain a two-way shape memory effect, in which a shape memory material spontaneously changes shape upon cooling as well as upon heating.

Alternatively, the deployable members 45-47 may be made from other metals and alloys that are biased, such that they may be restrained by the insertion tool 50 prior to deployment, but are inclined to return to their relaxed, expanded configuration upon deployment. Solely by way of example, the deployable members 45-47 may comprise other materials such as stainless steel, cobalt-chrome alloys, amorphous metals, tantalum, platinum, gold and titanium. The deployable members 45-47 also may be made from non-metallic materials, such as thermoplastics and other polymers. As noted above, the deployable members 45-47 may comprise any shape suitable for engaging and capturing lymph nodes, or engaging, grasping and/or abutting tissue, for purposes explained further below, and need not necessarily assume the curved shape depicted in FIGS. 1-2A.

Referring to FIG. 2B, the expandable devices 20 may be delivered to a target site in a patient’s anatomy in the contracted configuration using an insertion tool 50. In one embodiment, the insertion tool 50 comprises a needle-like body having a sharpened distal tip 52 and a hollow lumen 54, as shown in FIGS. 2A-2B. The insertion tool 50 may be manufactured from stainless steel or any other suitable material, and may comprise an endoscopic ultrasound (EUS), or echogenic, needle. Solely by way of example, the insertion tool 50 may comprise the EchoTip® Ultrasound Needle, or the EchoTip® Ultra Endoscopic Ultrasound Needle, both manufactured by Cook Endoscopy of Winston-Salem, N.C. Alternatively, the insertion tool 50 may comprise a non-echogenic needle, which may be visualized using an endoscope. As a further alternative, the insertion tool may comprise a conventional catheter 90 having at least one lumen sized to receive the expandable device 20, as depicted in FIGS. 8-9 below.

The hollow lumen 54 of the insertion tool 50 may comprise an inner diameter that is larger than an outer diameter of the expandable device 20. Therefore, the expandable device 20 may be loaded into the hollow lumen 54 in a delivery configuration, as shown in FIG. 2B. In the delivery configuration, the deployable members 45-47 of the expandable device 20 may comprise a substantially longitudinally-oriented profile, i.e., oriented along a longitudinal axis of the insertion tool 50. The expandable device 20 may be ejected from the insertion tool 50 by distally advancing a proximal region of the control member 30 while holding the insertion tool 50 steady, as explained in further detail below.

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The insertion tool 50 may comprise one or more markers 56, as shown in FIGS. 2A-2B, which may be disposed near the distal end of the insertion tool 50. The markers 56 may be configured to be visualized under fluoroscopy or other imaging techniques to facilitate location of the distal end of the insertion tool, for example, so that a physician may determine how far the insertion tool 50 has penetrated through a visceral wall, lymph node, or other matter, as explained further below. Optionally, a sheath member 58 having an inner diameter larger than an outer diameter of the insertion tool 50, as shown in FIG. 2A, may be longitudinally advanced over the insertion tool 50 to prevent inadvertent piercing of tissue.

Referring now to FIG. 3, the expandable device 20 described above may be used to capture, engage, and otherwise facilitate removal of a lymph node N from a bodily region, such as the mediastinal cavity M. In the exemplary method of FIGS. 4-12 described below, a selected lymph node N may be removed from the mediastinal cavity M via the esophagus E.

In FIG. 3, a patient’s trachea T and lungs L are shown for reference purposes. Multiple mediastinal lymph nodes N are shown in FIG. 3, including an uppermost mediastinal node above the left brachial vein, upper paratracheal nodes above the aortic arch and below the left brachiocephalic vein, lower paratracheal nodes in the vicinity of the aortic arch and main bronchus, and a paraesophageal node below the aortic arch. In FIGS. 4-12, an enlarged illustration focuses on removal of the paraesophageal node below the aortic arch. However, any lymph node N, either situated within the mediastinal cavity or in another bodily passage, may be engaged or captured using the apparatus and methods described herein.

Referring to FIG. 4, in a first step, an endoscope 70 is maneuvered into a patient’s mouth and down through the esophagus E. The endoscope 70 may comprise a dual-channel endoscope having first channel 72 and second channel 74. The first channel 72 may terminate at an exit port 73, while the second channel 74 may terminate at an exit port 75. While the lymph node procedure of FIGS. 4-12 may be performed using a single channel endoscope, it is preferred to utilize the multi-lumen endoscope 70.

The endoscope 70 may comprise an echo endoscope or other device suitable for imaging. When the endoscope 70 is positioned within the esophagus E, various lymph nodes N may be observed using ultrasound techniques. The endoscope 70 may be used to detect a node N suitable for treatment, such as a malignant node desired to be removed from the patient.

In a next step, after a suitable lymph node N had been detected, a first insertion tool 50 may be advanced distally through the first channel 72 of the endoscope 70 towards the target lymph node N. As shown in FIG. 5, the insertion tool 50 may be advanced distally through the exit port 73 of the endoscope 70 to pierce through the esophageal wall and through or around the target lymph node N. As noted above, the insertion tool 50 may comprise an EUS needle, such as the EchoTip® Ultrasound Needle, or the EchoTip® Ultra Endoscopic Ultrasound Needle, both manufactured by Cook Endoscopy of Winston-Salem, N.C. The sharpened distal tip 52 of the insertion tool 50 facilitates piercing through the target lymph node N. The markers 56 of FIG. 2A may facilitate in determining how far the insertion tool 50 has penetrated into and through the esophageal wall and the target lymph node N. Alternatively, the insertion tool 50 may be advanced around the target lymph node N, instead of directly through the node. Preferably, the sharpened distal tip 52 is advanced just distal to the target lymph node N, as depicted in FIG. 5.

It should be noted that during advancement and placement of the insertion tool **50** beyond the target lymph node N, the hollow lumen **54** of the insertion tool **50** may be loaded with a visceral anchor or tissue anchor (“T-anchor”) **80**, which is coupled to a suture **82**. The T-anchor **80** may be used for visceral wall stabilization, as explained in further detail below. As best seen in FIGS. **6-7**, the T-anchor **80** may comprise a crossbar having first and second ends, wherein the suture **80** is coupled to a central region of the crossbar between the first and second ends. One exemplary configuration of a T-anchor suitable for use in the present embodiments is described in greater detail in U.S. Patent Publication No. 2008/0132948, which is hereby incorporated by reference in its entirety. Another example of a suitable visceral anchor is disclosed in U.S. Pat. No. 5,123,914, which also is hereby incorporated by reference in its entirety.

Referring still to FIGS. **6-7**, with the insertion tool **50** disposed beyond the target lymph node N, the T-anchor **80** may be deployed. An inner stylet (not shown) may be disposed within the hollow lumen **54** of the insertion tool **50** at a location proximal to the T-anchor **80**. The inner stylet then may be advanced distally, while the insertion tool **50** is held steady, in order to distally eject the T-anchor **80** from the hollow lumen **54**, as depicted in FIG. **6**. It should be noted that during delivery of the T-anchor **80**, the suture **82** may be disposed within the hollow lumen **54** of the insertion tool **50**, as depicted in FIG. **6**, or alternatively may run along the outside of the insertion tool **50** within the first channel **72** of the endoscope **70**.

After the T-anchor **80** is ejected from the insertion tool **50**, the insertion tool **50** may be removed from within the first channel **72** of the endoscope **70**. At this time, the T-anchor **80** is disposed just distal to the target lymph node N, with the suture **82** disposed through the lymph node N and extending proximally through the first channel **72** of the endoscope **70**, as shown in FIG. **7**. The proximal end of the suture **82** may be manipulated by a physician to aid in stabilization, i.e., when the suture **82** is pulled proximally the T-anchor **80** may be tilted into a transverse position and may be caught by the lymph node N.

Referring now to FIGS. **8-9**, in a next step, the expandable device **20** of FIGS. **1-2B** may be delivered and deployed to engage, capture or otherwise facilitate removal of the target lymph node N. In this example, the expandable device **20** is loaded into a second insertion tool, which is in the form of a catheter **90** having a proximal end **92** and a distal end **94**. Alternatively, the expandable device **20** may be loaded through an insertion tool having a sharpened distal tip, such as an EUS needle similar to the insertion tool **50** described above. In a further alternative embodiment, the sheath member **58** described above, which may cover a sharpened insertion tool, may be used to deliver the expandable device in lieu of a separate catheter **90**.

The catheter **90** has a lumen disposed between the proximal end **92** and the distal end **94**. The expandable device **20** is loaded into the lumen of the catheter **90** in the delivery configuration shown in FIG. **2B**. It should be noted that the catheter **90** may be advanced directly over the suture **82** of the T-anchor **80** towards the target lymph node N. Therefore, both the suture **82** and the expandable device **20**, including the control member **30**, may be simultaneously disposed within the lumen of the catheter **90**, as depicted in FIGS. **8-9**.

Alternatively, a proximal region of the suture **82** outside of the body, or a distal region of the suture **82** near the visceral wall of the esophagus E, may be cut off prior to insertion of the device carrying the expandable device **20**. In this latter embodiment, if a new insertion device is used, such as a

different endoscope, needle or catheter, to deliver the expandable device **20**, then it may be advanced towards the visceral wall of the esophagus E without the need to be advanced directly over the suture **82** along its entire length.

As shown in FIG. **8**, the catheter **90** may be advanced over the suture **82** and beyond the target lymph node N. Preferably, the proximal end of the suture **82** is tensioned while the catheter **90** is advanced distally beyond the esophageal wall and the target lymph node N, as depicted in FIG. **8**. The tensioning of the suture **82** may retract the T-anchor **80** against the target lymph node N, which may facilitate stabilization of the node and advancement of the catheter **90** through the node. If necessary, the suture **82** can be locked into place to temporarily secure the tension and positioning the T-anchor **80**. Without the stabilization via the T-anchor **80** and associated suture **82**, the endoscope **70** may deflect away from the esophageal wall when the catheter **90** is advanced distally through the esophageal wall and lymph node N.

Referring to FIG. **9**, after the distal end **94** of the catheter **90** has been advanced beyond the target lymph node N, the expandable device **20** may be deployed by advancing the control member **30** distally with respect to the endoscope **70**. This causes the deployable members **45-47** of the expandable device **20** to extend distal to the distal end **94** of the catheter **90**. When the deployable members **45-47** are no longer radially constrained by the catheter **90**, they may assume their predetermined expanded configurations.

Referring to FIG. **10**, a cutting device **100** may be used to enlarge the esophageal wall opening to facilitate extraction of the target lymph node N. The cutting device **100** may comprise a needle knife having an electrified cutting tip **102**. The cutting device **100** may be advanced through the second channel **74** of the endoscope **70** towards the target site. An opening **105** may be carefully formed around the other components, including the catheter **90**, as shown in FIG. **10**. Optionally, the catheter **90** may be proximally retracted and removed prior to insertion or actuation of the cutting device **100**.

Referring to FIG. **11**, in a next step, the expandable device **20** may be proximally retracted, by retracting the control member **30**, to cause the deployable members **45-47** to engage, capture, or otherwise facilitate removal of the target lymph node N. In particular, the substantially 180-degree parachute-shaped configuration of the deployable members **45-47** may substantially or entirely surround the target lymph node N, then urge the target lymph node N in a proximal direction at least partially through the opening **105** and towards the lumen of the esophagus E. At about the same time, the suture **82** may be proximally retracted to retract the T-anchor **80** in harmony with the retraction of the target lymph node N and the expandable device **20**.

Referring to FIG. **12**, in a next step, the expandable device **20** may be removed from engagement with the target lymph node N. In a first exemplary technique, the catheter **90** may be advanced distally over the deployable members **45-47**, preferably while the T-anchor **80** is tensioned via the suture **82**, to cause the deployable members **45-47** to assume the contracted configuration of FIG. **2B**. The catheter **90** and control member **30** then may be proximally retracted to remove the expandable device **20** from engagement with the target lymph node N.

In a second exemplary technique, the deployable members **45-47** may pull through the target lymph node N and assume the retracted configuration of FIG. **2B** when a predetermined force threshold is exceeded. In this example, the deployable members **45-47** will not retract when engaging and capturing the lymph node N, but may be configured to retract when a predetermined force threshold is exceeded, e.g., when the

lymph node N is held in place against the catheter 90 and/or the endoscope 70. With the lymph node N held in place, further retraction of the control member 30 may force contraction of the deployable members 45-47 around or through the lymph node N and into the endoscope 70. In preliminary testing, the deployable members 45-47 may be contracted with a force in a range of about 0.5 pond to about 2.0 pond, although they may be tailored to contract upon any other suitable force.

At this time, the target lymph node N therefore is disposed partially or entirely within the esophagus E, with the suture 82 disposed through the lymph node N and the T-anchor 80 disposed distal to the lymph node N, as shown in FIG. 12. The cutting device 100 may be removed from the second channel 74 of the endoscope 70, and a removal device, such as a polypectomy snare, may be advanced through the second channel 74 and positioned to surround the target lymph node N. Electrocautery then may be used to cut the target lymph node N from the surrounding tissue. It should be noted that the suture 82 coupled to the T-anchor 80 also may be cut off by the removal device. The T-anchor 80 may be removed or may pass naturally through the body, while the remaining suture 82 may be pulled through the first channel 72 of the endoscope 70.

In a final step, the visceral wall opening 105 created during the procedure may be closed using known techniques. As an example, the opening 105 may be closed using a suturing system by placing multiple anchors around the opening 105, then tensioning the sutures in a purse-string fashion. Alternatively, clips or other devices may be used to effect closure of the opening 105. The closure of the opening 105 may be performed through the first channel 72 and/or the second channel 74 of the endoscope 70, which then is removed from the patient's body.

While FIGS. 4-12 have illustrated the use of one expandable device 20 for engaging, capturing or otherwise facilitating removal of a lymph node N located within the mediastinal cavity, the expandable device 20 disclosed herein may be useful in many other procedures performed through the stomach or other visceral walls. Further, the order of the method steps shown in FIGS. 4-12 may be varied, or some of the steps may be omitted. For example, while the use of the T-anchor 80 may be used for stabilization of the visceral wall and/or lymph node throughout the procedure, the T-anchor 80 may optionally be omitted.

Further, it will be appreciated that while a dual-channel endoscope 70 has been shown for performing the procedure, a single channel endoscope or other suitable insertion apparatus may be used to deliver the components and perform the procedure described above. Similarly, two different endoscopes may be used in succession, for example, a first endoscope may be used to detect a suitable lymph node, advance an EUS needle and deploy the T-anchor 80, while a second endoscope may be advanced to the target site over the suture 82 of the T-anchor 80 and used to deploy the expandable device 20 and complete the procedure.

Further, it may be desirable to only use the insertion tool 50 to deliver both the T-anchor 80 coupled to the suture 82 and the expandable device 20 coupled to the control member 30, without exchanging the insertion tool 50. In this example, the T-anchor 80 may be loaded within the hollow lumen 54 of the insertion tool 50 at a location distal to the deployable members 45-47. The suture 82 and the control member 30 may extend adjacent to one another within the hollow lumen 54. In use, distal advancement of the control member 30 may cause the deployable members 45-47 to be distally advanced to initially eject the T-anchor 80 from the distal end of the

insertion tool 50, for purposes described above. Then, at a subsequent desired time, the deployable members 45-47 may be ejected from the insertion tool 50. In this example, therefore, only one insertion tool 50 is used and does not need to be exchanged.

Referring now to FIGS. 13-14, in an alternative embodiment, the expandable device 20 may be adapted to anchor into a visceral wall and/or other tissue to facilitate stabilization during a transluminal procedure using the dual-channel endoscope 70. In a first method step, an insertion tool 50, such as an EUS needle, is distally advanced through the first channel 72 of the endoscope 70 and pierces through the esophageal or other visceral wall, as generally set forth above. In this embodiment, the hollow inner lumen 54 of the insertion tool 50 may be loaded with the expandable device 20. Upon desired placement of the insertion tool 50, the control member 30 coupled to the expandable device 20 is advanced distally with respect to the insertion tool 50. This causes the deployable members 45-47 of the expandable device 20 to extend distal to the insertion tool 50 and assume their predetermined expanded configurations, as shown in FIG. 13.

The insertion tool 70 then may be retracted into the first channel 72 of the endoscope 50, and the deployable members 45-47 then may be retracted proximally by retraction of the control member 30. This causes the deployable members 45-47 of the expandable device 20 to engage, penetrate, abut or otherwise anchor into an outer portion 107 of the visceral wall. While a transluminal procedure is shown performed through the esophagus, other visceral wall, such as the stomach wall, may be perforated.

Such anchoring by the deployable members 45-47 of the expandable device 20 promotes stabilization of the system when additional components are advanced, or procedures performed, through the first channel 72 and/or the second channel 74 of the endoscope 70. The expandable device 20 also may reduce the likelihood of the endoscope 70 deflecting away from the visceral wall as other components are advanced distally from the endoscope 70.

For example, in the case of lymph node removal, a first expandable device 20 may be deployed through the first channel 72 to help stabilize the system, and then a second expandable device 20 may be deployed through the second channel 74 to facilitate removal of the lymph node, as described above. In this case, the first expandable device 20 may stabilize the endoscope 70 while the lymph node is cut and closing devices, such as anchors, are placed for closing the opening in the visceral wall.

Upon completion of the procedure, further retraction of the control member 30 may cause the deployable members 45-47 to pull through the visceral wall and assume the retracted configuration, shown in FIG. 2B, within the first channel 72 of the endoscope 70. As noted above, the deployable members 45-47 may assume the retracted configuration by advancing the insertion device 50 or catheter 90 distally, or it may pull through the visceral wall and assume the retracted configuration of FIG. 2B when a predetermined force threshold is exceeded. Subsequently, any visceral wall openings formed during the procedure may be closed using known techniques, for example, purse-string suturing or clipping.

Referring now to FIG. 16, in an alternative embodiment, an expandable device 20' comprises an additional capture member 125. The capture member 125 may comprise one or more wires coupled to the deployable members 45-47, for example, in the form of a flexible and expandable netting disposed between the deployable members 45-47, to facilitate engagement with and removal of a lymph node upon retraction of the expandable device 20'. The capture member 125 may be

soldered or welded to selected regions along the deployable members 45-47, e.g., in the vicinity of the respective apices 48 and distal tips 49.

Referring now to FIGS. 17-19, a control assembly 200 that may be removably coupled to a handle 170 is described. In FIG. 17A, a proximal region 31 of the control member 30, which as described above may be coupled to deployable members 45-47, extends proximally from the handle 170. The handle 170 may be coupled to the proximal end of the insertion tool 50 described above, and the control member 30 may extend through the hollow lumen 54 of the insertion tool 50, as explained above.

The control assembly 200 generally comprises a platform 202 having guide elements 220a and 220b, which may be in the form of longitudinally-oriented tracks. The guide elements 220a and 220b guide longitudinal movement of a slidable actuator 210 between unlocked and locked states, as shown in FIGS. 17A-17B, respectively. As shown in FIG. 19, a surface of the slidable actuator 210 comprises grooves 212a and 212b, which are configured to securely slide along the guide elements 220a and 220b of the platform 202.

The control assembly 200 further comprises tubing 230 extending between the guide elements 220a and 220b along at least a portion of its length. As shown in FIGS. 18A-18B, the tubing 230 may comprise a lateral bore 233 formed therein, which is generally sized to receive a stopper 250. Notably, in FIGS. 18A-18B, the slidable actuator 210 has been removed from the platform 202 for illustrative purposes, while in FIG. 18B, the stopper 250 has been removed from the bore 233 of the tubing 230 for illustrative purposes.

The control assembly 200 further comprises an engaging region 240, which may partially surround the tubing 230, as shown in FIG. 17A. The engaging region 240 of the control assembly 200 may engage a proximal region 175 of the handle 170, as shown in FIG. 17B. For example, threading 242 on the engaging region 240 may engage complementary threading (not shown) on the proximal region 175 of the handle 170.

When the control assembly 200 is unattached to the handle 170, as shown in FIG. 17A, an exchange of components may take place. For example, after the deployable members 45-47 coupled to the control member 30 have engaged a lymph node or other tissue, as explained above, the insertion tool coupled to the handle 170 may be proximally removed over the length of the control member 30. Subsequently, another insertion tool may be distally advanced over the control member 30, while the control member 30 and the deployable members 45-47 remain engaged with the lymph node or other tissue.

If it becomes desirable to proximally advance or retract the control member 30, and thus the deployable members 45-47, along with the handle 170, then the control assembly 200 is coupled to the handle 170 as shown in FIG. 17B. The slidable actuator 210 then is distally advanced along the guide elements 220a and 220b, as described above. Notably, the slidable actuator has a distal end 215 having a relatively deep recess, which tapers to a relatively shallow recess at a proximal end 216, as shown in FIG. 19. Thus, with distal advancement of the slidable actuator 210, a shallower region of the slidable actuator 210 begins to cover the stopper 250, and the underside of the slidable actuator 210 progressively engages the stopper 250. The slidable actuator 210 therefore urges the stopper 250 radially inward in the position shown in FIG. 17B, and the stopper 250 presses radially inward upon the tubing 230. Since the proximal region 31 of the control member 30 is disposed within the tubing 230, inward compression of the tubing 230, via the stopper 250, pinches upon the control member 30. In this state, the control assembly 200

securely grasps the proximal region 31 of the control member 30 positioned adjacent to the bore 233. Optionally, a cannula 180 may be soldered or otherwise secured to the proximal region 31 of the control member 30 to provide a locally increased profile that may facilitate grasping of the control member 30 by pinching of the tubing 230. When it is desired to remove the handle 170 and insertion tool again, the slidable actuator 210 is moved back proximally to the state of FIG. 17A, thus releasing the stopper 250 and the engagement of the tubing 230 with the control member 30.

While various embodiments of the invention have been described, the invention is not to be restricted except in light of the attached claims and their equivalents. Moreover, the advantages described herein are not necessarily the only advantages of the invention and it is not necessarily expected that every embodiment of the invention will achieve all of the advantages described.

We claim:

1. A method for facilitating removal of a lymph node, the method comprising:

providing an expandable device comprising at least one deployable member having contracted and expanded states;

advancing at least a portion of the expandable device beyond the lymph node with the deployable member in the contracted state;

deploying the deployable member at a location distal to the lymph node, wherein the deployable member begins to deploy distal to the distal end of the lymph node, and wherein the deployable member, in the expanded state, comprises a configuration sized to at least partially circumferentially surround the lymph node; and proximally retracting the expandable device to cause the deployable member to engage the lymph node.

2. The method of claim 1 wherein advancing at least a portion of the expandable device through the lymph node further comprises:

advancing an insertion tool through the lymph node, wherein the insertion tool comprises a hollow lumen, and wherein the expandable device is disposed within the hollow lumen with the deployable member in the contracted state; and

advancing the deployable member distal to the insertion tool to cause the deployable member to expand.

3. The method of claim 2 wherein the deployable member self-expands into a parachute-shaped configuration in the expanded state when no longer constrained by the insertion tool.

4. The method of claim 1 further comprising:

providing a T-anchor coupled to a suture, wherein the T-anchor is disposed within a hollow lumen of an insertion tool;

advancing the insertion tool distally beyond the lymph node;

ejecting the T-anchor from the insertion tool at a location distal to the lymph node; and

retracting the suture to cause the T-anchor to engage the lymph node and promote stabilization of the lymph node.

5. The method of claim 4, further comprising:

removing the insertion tool from within the lymph node;

providing a catheter having a lumen, wherein the expandable device is disposed for delivery within the lumen of the catheter; and

distally advancing the catheter through the lymph node while tensioning the suture to stabilize the lymph node.

6. The method of claim 1, wherein the lymph node is removed transluminally through a visceral wall, the method further comprising:

creating an opening in the visceral wall to facilitate removal of the lymph node,

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engaging the lymph node with the expandable device and retracting the expandable device to move the lymph node in a proximal direction through the visceral wall.

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